MAILING OF BIOLOGICAL TOXINS

JOINT HEARING

BEFORE THE

SUBCOMMITTEE ON
POSTAL PERSONNEL AND MODERNIZATION

OF THE

COMMITTEE ON
POST OFFICE AND CIVIL SERVICE

AND THE

SUBCOMMITTEE ON
RESEARCH AND DEVELOPMENT

OF THE

COMMITTEE ON ARMED SERVICES
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MAILING OF BIOLOGICAL TOXINS

THURSDAY, JUNE 23, 1988

HOUSE OF REPRESENTATIVES, SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION, COMMITTEE ON POST OFFICE AND CIVIL SERVICE, AND SUBCOMMITTEE ON RESEARCH AND DEVELOPMENT, COMMITTEE ON ARMED SERVICES,

Washington, DC.

The subcommittees met, pursuant to call, at 1:30 p.m., in room 311, Cannon House Office Building, Hon. Frank McCloskey (chairman of the Subcommittee on Postal Personnel and Modernization) presiding.

Mr. MCCLOSKEY. Good afternoon. The joint hearing of the House Subcommittee on Postal Personnel and Modernization and the Armed Services Subcommittee on Research and Development will come to order.

We are very pleased to welcome our distinguished witnesses today.

In the last year, a vial of living samples of Crimean-Congo Hemorrhagic Fever virus was lost in the U.S. Postal System. One year later this material has still not been located. Other incidents have since occurred causing me extreme concern as to the safety of mailing and other transportation methods that are being used by DOD in our nation's biological defense research program.

I have been told as recently as today that there have been at least several other instances, although the material was not toxic.

Last November, near panic occurred at one postal facility when a vial of unidentified biological material leaked onto the bare hands of a postal employee. Although the material in this instance was non-toxic, the inadequacy of training, safety precautions and emergency procedures for the transport of hazardous biological toxins illustrates the risk involved in mailing these substances.

There are reports of allegedly super-sealed containers opening and of vials of biological materials becoming separated from their packaging materials during handling by postal employees. In addition, the California Attorney General has questioned the logic of Department of Defense mailings of toxic materials.

Our first witness today, Senator Carl Levin, issued a preliminary report last month which uncovered serious deficiencies in DOD management of safety issues concerning biological toxins.

Today the Post Office and Civil Service Subcommittee on Postal Personnel and Modernization is conducting a joint oversight hearing into this matter with the Armed Services Subcommittee on Research and Development.

Although I do not wish to jeopardize or impair the research and diagnostic capabilities of the nation's scientific community, the gravity of potential accidents warrants that every possible safeguard and precaution be implemented when transporting this material. In addition, the risk associated with extremely toxic substances would dictate a separate consideration from normal medical cultures.

During briefings in the past two weeks, the Department of Defense displayed an apparent lack of concern about the safety procedures followed by Department of Defense contractors in mailing this material. I believe the Department of Defense needs to take an active leadership role in developing and verifying the implementation of a uniform system of transporting this material.

I am concerned with the disastrous effects which could result from any accident involving these toxins. Accidents happen despite the most conscientious, well-monitored and extensive precautions that can be taken. Remember the Space Shuttle disaster and the accident at Three Mile Island. Anthrax was also leaked in the Soviet Union. Accident prevention and risk control programs were in operation in these cases and the planners calculated the risk of such accidents as negligible.

I hope today's hearing will shed some light on what exactly is being sent through the mails and whether or not the Postal Service is the best means of transportation for these biological agents.

I would like to thank all of our witnesses for appearing today and in particular Mr. Gerald Miss from the Frederick, Maryland, post office, who will have very interesting testimony later.

I want to also thank my Armed Services colleagues, Chairman Aspin and Governor Brennan, for their participation in this important hearing.

I would like to welcome Senator Levin. I understand you and your committee have been working on these and related issues for two years now. We appreciate your advice and guidance.

Before you begin your testimony, the statements of Congressman Aspin and Congressman Dickinson will be in the record, as though presented in full.

STATEMENT OF HON. LES ASPIN

Mr. ASPIN. Lately the shipment of biological agents through the postal system has received a lot of press coverage. Much of the publicity has to do with the Defense Department shipment of biological warfare agents.

There are a number of committees looking into different aspects of this issue. For example, the House Armed Services Committee, in a joint hearing with the Foreign Affairs Committee, has already held a hearing on the Dugway environmental impact statement. Also Senator Carl Levin has done a study on the overall safety in laboratory handling of toxic agents and this summer several other committees plan to hold hearings on other aspects of the issue.

After Senator Levin talks about his overall safety study today, I would like to see this hearing focus only on the transportation safety issue. Specifically, (a) is the Army packaging concept adequate; (b) how does the Army packaging concept relate to the

Center for Disease Control [CDC] packaging requirement (42 CFR; (c) how does the Army and CDC monitor and enforce the various packaging requirements; and (d) if there is a problem, are there alternative methods of shipping these agents?

STATEMENT OF HON. WILLIAM L. DICKINSON

Mr. DICKINSON. With all the press coverage this issue is receiving, mailing biological agents is becoming somewhat of a political issue. The purpose of this hearing is to find out if there is also a safety issue. I agree with the chairman that the focus of this hearing should be the transportation issue. I understand that shipping bio agents goes beyond the DOD as it also includes non DOD shipments between private laboratories, universities and hospitals. So when we look at this issue we have to also evaluate if it is a DOD issue or is it an industry-wide potential problem. If it is an industry-wide issue, then who is responsible for action and how can the DOD be of assistance? How would the nation respond to an accident?

We are pleased to have two of our colleagues with us today, Senator Levin and Representative Pelosi. We are looking forward to hearing your testimony. Thank you.

STATEMENT OF HON. CARL LEVIN, A U.S. SENATOR FROM THE STATE OF MICHIGAN

Senator LEVIN. Mr. Chairman, let me thank you and congratulate you and both of the committees for putting together this hearing on a very, very important subject.

As you have indicated, our subcommittee over at the Senate has been working almost two years now with a somewhat broader subject, not only the mailing of these materials but also the way they are handled in laboratories.

A preliminary report of the Majority staff has been issued. We ask that that be made a part of the record, if that is appropriate.

Mr. MCCLOSKEY. Without objection.

[The information follows:]

PRELIMINARY REPORT
OF THE MAJORITY STAFF OF THE
SENATE SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT
ON DOD'S SAFETY PROGRAMS FOR
CHEMICAL AND BIOLOGICAL WARFARE RESEARCH

May 11, 1988

In late 1986, at the direction of Senator Carl Levin (D-Mich.), chairman of the Senate Subcommittee on Oversight of Government Management (OGM Subcommittee), the OGM staff began a review of laboratories performing research for the Department of Defense (DOD) in the area of chemical and biological warfare (CBW). The purpose of the review was to examine the extent to which DOD is ensuring that CBW research is being conducted in a safe manner.

For 18 months, the OGM staff interviewed numerous persons knowledgeable in the CBW field, including DOD and other federal personnel, university scientists and private organizations. The staff reviewed thousands of pages of documents including annual and special CBW reports, CBW contracts, federal rules governing CBW research and the handling of hazardous materials, fire and safety codes, and accident reports.

Over the course of the investigation, the OGM staff uncovered serious deficiencies in DOD's management of safety issues in the CBW research program, including inadequate regulations, lax safety enforcement, and documented safety lapses. These deficiencies exist at the same time that the CBW research program is experiencing a period of rapid growth, with an increase in annual funding of more than 500% since 1980.

This preliminary report does not examine the current safety practices of particular facilities conducting CBW research. Nor does it reach final conclusions as to whether, currently, CBW research is being conducted in a safe manner. Rather, the report addresses DOD's management of safety issues -- what DOD knows and does about safety and the extent to which it exercises safety oversight in the CBW research program. The majority staff's preliminary conclusion is that DOD's management controls in the area of safety have serious failings. Among other problems, DOD appears to lack the necessary information and organizational apparatus even to evaluate the safety of a significant number of laboratories participating in the CBW research program.

In light of these deficiencies, the majority staff recommends that the OGM Subcommittee schedule hearings to examine what should be done to improve DOD's safety programs for CBW research.

Increasing Safety Risks

CBW research is an inherently dangerous proposition, and the risks are increasing.

The CBW research program plans and funds research related to both chemical warfare and biological warfare. The chemical warfare portion of the program funds the development of weapons and defensive measures. By treaty, the biological warfare portion of the program is restricted to developing defensive measures; the United States is not permitted to develop biological weapons. The biological portion of the program is thus known as the Biological Defense Program (BDP).

Chemical warfare (CW) involves the use of lethal or incapacitating chemical compounds for military purposes. The primary CW agents are blistering agents which destroy skin tissue and mucous membranes, blood agents which block or hinder the blood's ability to supply oxygen to the body, choking agents which attack the respiratory system, and nerve agents which attack the nervous system. Examples are mustard gas, hydrogen cyanide, phosgene and soman. Exposure to CW agents causes such incapacitating or lethal effects as blisters, burns, convulsions and asphyxia.

Biological warfare (BW) involves the use of living organisms for military purposes. BW agents include viruses, bacteria, fungi, rickettsia, and protozoans. Examples are Q fever, tularemia, rift valley fever, lassa fever, and eastern equine encephalitis. BW agents can cause either immediate or delayed symptoms, with incapaciting or lethal results, such as dizziness, shortness of breath, nausea, vomiting, fever, chills, blisters, convulsions, diarrhea and hemorrhaging.

A third category of CBW agents involves the military use of toxins. Toxins are poisonous chemical compounds derived from living organisms. Examples are snake venom, mycotoxin (poisons produced by fungi), scorpion toxin and marine toxins. These substances can be treated as CW or BW agents. Previously, toxins were not a significant element of CBW research due to the difficulty of obtaining sufficient research quantities. Now, new laboratory techniques permit the rapid, synthetic production of many toxins. Their effects on human beings are similar to those for BW agents.

The safety risks inherent in CBW research begin with the agents themselves. They are highly dangerous, involving many of the most deadly substances known. Hydrogen cyanide and certain snake venoms, for example, can kill a human being in minutes. Some BW agents, despite years of research, produce illnesses with no known cure. Even minute amounts of some CBW agents cause health hazards; in the case of many BW agents, the escape of even microorganisms must be prevented. If adequate safety precautions are not in place, a CBW agent can leak down an unprotected drain into ground water, blow through an unprotected ventilation shaft into the wind, escape on a laboratory worker's clothing, fly out with a wandering mosquito, or spill out of a container due to a shipping accident, natural disaster or terrorist attack. Once outside, some CBW agents, such as nerve agents and anthrax, can persist in the environment for years.

Second, the type of research being performed with CBW agents heightens safety concerns. In the CW area, for example, some research projects involve work with explosives. In both CW and BW experiments, the research may necessitate work with radioactive substances, unpredictable animals and clumsy safety equipment.

A third factor increasing safety concerns involves new biotechnology techniques which, for example, permit the mass production of CBW agents and the propagation of novel -- and even more deadly -- substances. In a May 1986 report to the House Appropriations Committee, DOD described the impact that these techniques have had on CBW research:

> Perhaps the most significant event in the history of biological weapons development has been the advent of biotechnology. It enables the development of new microorganisms and products with new, unorthodox characteristics. Inserting BW related genetic traits into natural infectious microorgansisms can potentially result in agents with greater virulence, antibiotic resistance, and environmental stability; and altered immuno protection and serological identification. . . . Bacteria and yeasts, genetically altered to produce . . . toxins . . . are miniature factories by virtue of their ability to proliferate rapidly. Large quantities of compounds, previously available only in minute amounts, thus become available at relatively low cost.

Report, Chapter 1, at 7-8. Due to the new techniques, DOD predicted the creation of BW agents which would "maximize infectivity and pathogenicity" as well as "environmental stability, persistency and potency"; BW agents which are immune to existing vaccines; and BW agents which attack the body through bioregulators that control perception, mood, organ function, body temperature and other body processes.

Id. at 8. DOD is charged with finding defenses to such agents.

The advent of genetic engineering and other techniques raise safety concerns that were not present in earlier CBW research efforts. They enable the overnight production of huge quantities of CBW agents and require work with even more deadly substances that may be able to live even more easily outside the laboratory. As these techniques and work with novel agents become more common in CBW research, DOD's safety programs need to keep pace.

In addition to dangerous substances, risky experiments and new technologies, still another factor has increased the risks of CBW research -- DOD's rapid expansion of the program.

In recent years, DOD spending on CBW research has increased dramatically. Annual reports published by DOD indicate that, during the years 1980 to 1986, annual CBW research funds have increased by more than 500%, from about $63 million in 1980 to about $348 million in 1986. (Spending on CW research has increased from about $47 million to $257 million; spending on BDP research has increased from about $16 million to more than $90 million.) See Exhibits A and B. From 1980 to 1986, DOD funds for CBW research have totalled more than $1.5 billion.

The number of laboratories performing CBW research for the federal government has also increased dramatically. Documents in the possession of the OGM staff indicate that about 150 public and private laboratories are now involved in DOD-funded CBW research. These laboratories appear to be located in more than 30 states, the District of Columbia and 15 countries. They include prestigious universities, small biotechnology firms and large companies, in cities and suburbs throughout the United States.

The rapid increase in CBW funding and laboratories means that more CBW research involving more facilities is taking place in more locations throughout the country. It means there are not only more opportunities for accidents, but also that there is an increase in agent quantities and in the transport and handling of hazardous materials that the government should monitor. Further, the rapid pace of expansion means each CBW research project has to compete harder for the attention and limited resources of the DOD personnel charged with monitoring the research program.

The latest example of DOD's attempt to expand the CBW program is its proposal to build a Biological Aerosol Test Facility (BATF) at Dugway Proving Ground in Utah. The BATF is the first CBW facility designed for full-scale aerosol testing of BW agents. Aerosols of BW agents are particularly

dangerous, not only in terms of infecting laboratory workers, but also in terms of BW agents escaping the confines of a facility. The BATF has not yet been built due to objections by a number of organizations and individuals.

In sum, the dangerous nature of the CBW research program -- involving inherently dangerous agents and experiments, a rapidly expanding program, and the presence of CBW research projects throughout the United States -- indicates that a review of safety concerns is needed at this time.

Who Conducts CBW Research

DOD is the key federal agency responsible for CBW matters. Within DOD, the Army has been assigned lead responsibility for the CBW program, including research, procurement, training, policy development and budgeting. The Army plans and coordinates the CBW research program, doing much of the work itself, although it has delegated certain projects to other DOD components such as the Navy.

Within the Army, the lead component responsible for researching chemical weapons and CBW defensive measures (such as the Bigeye bomb, protective clothing, shelters, and detectors) is the Army Material Command (AMC). The lead component responsible for conducting CBW defensive medical research (such as developing vaccines for BW agents, antidotes for CW agents, and chemical and biological profiles of various substances) is the Army Medical Research and Development Command (MRDC).

Each of these two commands sponsors CBW research facilities. Within the AMC, the leader in CW research is the Chemical Research, Development and Engineering Center (CRDEC) at Aberdeen Proving Ground, Maryland. A second CBW facility is the Natick Research, Development and Engineering Center (NRDEC) at Natick, Massachusetts. Within MRDC, the leader in BW defensive medical research is the US Army Medical Research Institute for Infectious Diseases (USAMRIID) at Fort Detrick, Maryland, while the leader in CW medical research is the US Army Medical Research Institute for Chemical Defense (ICD) at Aberdeen Proving Ground.

All four of the DOD facilities, CRDEC, NRDEC, USAMRIID and ICD, possess a sizeable research complex, with multiple labs, storage facilities, administrative offices, shipping facilities, and numerous professional, clerical and other employees. They perform the bulk of DOD's in-house CBW research, although several other DOD laboratories also have CBW projects.

In addition to DOD's in-house research facilities, a signficant amount of CBW research is performed by laboratories working under contract with DOD. In fact, since

1980, these contractors have increased their share of CBW research funds. In 1980, for example, the split between DOD and contractor facilities for CBW research funds was 60% to 40%, with federal laboratories getting the greater share. By 1986, that ratio has been reversed. See Exhibit C.

It is worth noting here that a number of non-DOD federal agencies also perform or oversee CBW research, usually using DOD funds. They include the Department of Commerce (its National Oceanic and Atmospheric Administration sponsors research on marine toxins which DOD funds), Department of Energy (performs several CBW research projects), Department of Health and Human Services (its Center for Disease Controls and Food and Drug Administration each perform CBW research projects), Department of Labor (its National Institute for Occupational Safety and Health helps research safe destruction of chemical munitions), Department of State (sponsors research to develop CBW detectors), National Aeronautic and Space Administration (sponsored a disease surveillance project), and Veterans Administration (several VA hospitals perform CBW medical research).

What Rules Govern CBW Research

The rules governing CBW research are lengthy, complex and interrelated. Here is a partial list:

Treaties -- There are two major CBW treaties which the United States has signed and ratified. The first treaty, drawn up in 1925, prohibits signatories from engaging in first use of CBW weapons during war, but contains no prohibition on research, development or possession of CBW weapons. The second treaty, drawn up in 1972, prohibits signatories from developing or possessing BW agents or weapons, but permits signatories to engage in BW research for protective purposes. It is due to these treaties that the United States possesses chemical weapons and sponsors chemical warfare research into both offensive and defensive measures, but possesses no biological weapons and restricts BW research to developing defensive measures.

50 USCS Chapter 32, CBW Program -- This is the key statute in the US Code which addresses CBW. It requires DOD to submit annual reports on CBW research, mandates safe disposal of CBW agents, restricts testing of CBW agents on civilian populations and in open air experiments, requires notice to Congress of experiments on humans, requires notice to other countries before delivering CBW agents or weapons, requires destruction of the obsolete chemical munitions stockpile and limits future chemical weapons to binary munitions.

Army Regulation 50-6, Chemical Surety Program -- This is the key regulation for DOD laboratories and contractors performing research with CW agents, called "chemical surety material" or CSM. It provides rules on safe laboratory practices, security requirements, emergencies, procedures for storage, transportation and disposal of CSM, and other matters. It also assigns oversight and safety responsibilities to particular DOD officials. This regulation does not apply to research involving only BW agents.

CDC-NIH rules on Biosafety in Microbiological and Biomedical Laboratories ["CDC-NIH Biosafety Rules"]; NIH Guidelines for Research Involving Recombinant DNA Molecules ["NIH Guidelines"] -- The CDC-NIH Biosafety Rules provide voluntary guidelines for laboratories performing research with infectious agents, including BW agents. Essentially, they establish four classes of experiments based upon the type of agents and research techniques to be used, and specify certain containment facilities and safety procedures for each class. (Class 4 experiments require maximum safety precautions.) Using essentially the same system, the NIH Guidelines classify experiments involving genetic engineering into one of the 4 categories, specify the safety precautions for each class, and mandate a biosafety committee in every laboratory to oversee its genetic engineering work. DOD has not made the CDC-NIH Biosafety Rules mandatory for CBW research, but does require all DOD research involving genetic engineering to comply with the NIH Guidelines. This requirement -- which affects about 10% of the BDP research contracts -- mandates safety precautions for those research projects. For the remaining 90% of BDP contracts -- projects which involve BW agents but no genetic engineering -- DOD apparently expects laboratories to follow the CDC-NIH Biosafety Rules, but no regulation requires them to do so.

Federal Acquisition Regulation (FAR) -- The FAR governs federal contracts. Some FAR rules have particular significance for CBW research contracts, including those on insurance and requirements to follow federal laws governing the transportation, handling and disposal of hazardous materials.

Standard Operating Procedures/Laboratory Safety Plans -- Most laboratories have a set of written procedures (sometimes called protocols) which are uniquely adapted to their facilities and address safe laboratory practices. Each of DOD's major CBW research facilities has such a set of rules. Each contractor working with CW agents is required, under the Chemical Surety Program, to submit to DOD for approval certain written

safety plans; however, contractors working with BW agents do not have a comparable requirement.

CBW Safety

The OGM staff was unable to locate a comprehensive safety program for CBW research, that is, a readily identifiable set of safety regulations and an office with overall safety responsibilities. Instead, the staff found two very different approaches to safety divided along chemical and biological lines.

Biological Defense Program. With respect to research involving BW agents, DOD's safety protections appear to be fragmented and, particularly for BDP contractors, completely inadequate. There is no comprehensive set of safety regulations for research with BW agents and toxins, no emphasis on safety in the contractor program, and no office that monitors contractor safety.

The lack of adequate safety regulations is particularly startling. The need for safety precautions is beyond dispute. As indicated earlier, BW agents are among the most deadly organisms known. And accidents do happen. The Army's leading BDP facility, USAMRIID, for example, has experienced fire in a high containment laboratory, misplaced vials of BW agents, laboratory spills and employee exposures to BW agents.

The CDC-NIH Biosafety Rules identified earlier establish a general framework for safe research with biological agents. Use of biosafety committees, four classifications of experiments, and differing levels of safety precautions for each class, have gained widespread acceptance among biological researchers. Among the safety precautions are requirements for laboratory containment facilities, rodent and insect control programs, special laboratory equipment, ventilation systems, warning signs and protective clothing; rules on restricting entry to work areas, taking showers, consuming food in the laboratory, storing biological agents, and destroying or decontaminating laboratory materials; systems to monitor the laboratory environment, the safety equipment and the employees' health; and procedures to prevent or respond to emergencies including vaccinations, quarantines, and medical treatment. While not conclusive on all aspects of safety applicable to research with BW agents and toxins, these rules go much of the way towards establishing a comprehensive safety scheme.

Despite their widespread acceptance, the CDC-NIH Biosafety Rules are not mandatory for either DOD laboratories or contractors performing research with BW agents and toxins. Nor has the BDP issued its own comprehensive safety rules governing research with BW agents and toxins.

Instead, the BDP treats safety in a piecemeal fashion, with scattered rules and incomplete regulations. For example, Army Regulation 70-65 requires each Army research facility using biological agents to establish its own safety rules. The regulation does not mention BW agents or toxins, nor does it contain requirements for coordinating, reviewing or updating the rules produced by each facility. USAMRIID is one example of an Army facility which has developed its own safety rules.

For BDP contractors, DOD appears to have imposed a safety rule across the board only for BDP contracts which involve genetic engineering. Such research must comply with the NIH Guidelines. But for the 90% of BDP contracts that do not involve genetic engineering, DOD imposes no mandatory safety rules, not even requirements that contractors establish their own safety programs, that they comply with recognized safety rules, or that they certify that they employ safe laboratory practices in connection with BW agents and toxins.

Examples of BDP research which do not involve genetic engineering and so appear to be outside any mandatory safety rules are experiments which define the characteristics of BW agents and toxins or which seek to identify unknown pathogens collected from CBW battlefields. In such cases, a contractor appears to be under no legal obligation to possess the proper containment facilities, to monitor its laboratory environment and workers, to report accidents to DOD, or to decontaminate its facilities when the research is complete.

In addition to the regulatory gap, the OGM staff has been unable to locate a safety office in the BDP program with the mission of ensuring safe laboratory practices by all facilities performing research with BW agents and toxins. The OGM staff did find that USAMRIID had its own safety office, consisting of a biosafety officer and two assistants. However, these persons are responsible only for monitoring USAMRIID's operations. While they are available for consultation by other facilities and, on occasion, have advised BDP contractors on biosafety issues, none are assigned the responsibility of monitoring the safety of off-site DOD and contractor laboratories.

The absence of BDP safety personnel means there appear to be no safety inspections of BDP contractors prior to contract awards. On occasion, MRDC or USAMRIID contracting personnel or scientists may conduct a pre-award, on-site visit to evaluate a BDP contractor's facilities. However, these visits apparently are not designed to be safety inspections; formal safety inspections do not appear to take place routinely; and the persons visiting the sites appear not to be safety specialists. There appears to be no

requirement that BDP contractors submit written safety plans for approval. After a contractor receives an award, there appears to be no requirement that BDP personnel conduct periodic safety inspections of the contractor's operations, and routine safety inspections do not appear to be performed. There are no safety reports required by DOD to be maintained for the contractors' laboratories. There is no BDP accident reporting system and no accident reports filed by BDP contractors. When a contractor leaves the BDP program, there appears to be no requirement that DOD certify decontamination of the contractor facilities. USAMRIID personnel indicate no BDP contractor has ever been terminated for unsafe practices.

In short, there appear to be no BDP personnel who are actively engaged in ensuring that BDP contractors employ safe laboratory practices. When combined with the poor regulatory scheme, the facts indicate there is simply no active safety program within DOD for contractors performing BDP research.

While it is possible that all laboratories performing research with BW agents and toxins are voluntarily employing safe practices, DOD cannot be sure of that or that such voluntary efforts are adequate, without exercising safety oversight. The key issues warranting further attention, then, are whether DOD should implement mandatory safety requirements for BDP research and, if so, what safety protections would be appropriate.

In 1987, a federal district court ordered DOD to prepare an Environmental Impact Statement (EIS) for the Biological Defense Program. Preparation of the EIS, due in May, is expected to have caused DOD to evaluate the overall safety of the BDP. The OGM staff was told that its preparation caused BDP personnel to conduct safety inspections of about a dozen laboratories. However, the extent to which the EIS addresses safety issues is not yet known, since it has not yet been publicly released. Distribution of that report should add to the Subcommittee's knowledge of BDP safety issues.

Chemical Surety Program. The approach to safety for research involving CW agents, while better than that for BDP research, also appears to have major shortcomings.

In contrast to the BDP, there is a comprehensive set of safety rules for research involving CW agents. The relevant regulation, identified previously, is the Chemical Surety Program, Army Regulation 50-6. It controls the possession, handling and disposal of chemical surety material (CSM). CSM is defined as "all lethal and incapacitating chemical agents that are either adopted or being considered for military use."

The Chemical Surety Program applies on its face to all in-house Army research facilities handling CSM. It also applies to all contractors handling CSM, through the Army's inclusion of extensive clauses in contracts where use of CSM is contemplated. Among the CSM safety rules which DOD laboratories and contractors must follow are: designation of a chemical safety officer and CSM custodian; written safety plans which, for contractors, must be approved by DOD; specified ventilation systems, protective clothing and emergency equipment; and specified procedures for transporting and storing CSM, keeping inventories and other records, monitoring personnel, equipment and the laboratory environment, performing experiments involving CSM, reporting accidents, and ensuring personnel and physical security.

Also in contrast to the BDP program, the OGM staff was able to locate two DOD offices responsible for monitoring safety in CW research. Staffed with safety and security specialists, one office is administered by the CRDEC, the other by ICD. The CRDEC safety office, with 26 employees, monitors CRDEC, several off-site government laboratories and about 15 contractors. The ICD safety office, called the Safety and Chemical Operations Office, is much smaller with 8 employees. It monitors ICD and about 38 off-site contractors.

The two offices perform several safety functions. They conduct on-site inspections of laboratory facilities prior to receipt of CSM, review and approve written safety plans, and conduct periodic safety inspections of laboratory facilities after receipt of CSM. For laboratories using undiluted CSM, the safety offices conduct annual accident drills, called a Chemical Accident/Incident Response exercise. Each inspection and accident drill is written up in a report maintained by the safety office that performed it. These reports include checklists identifying the items inspected and narrative descriptions of problems found. On occasion, follow-up inspections are performed at troubled sites. Finally, laboratories who decide to halt participation in CSM research must decontaminate their facilities and be certified as clean by the safety offices.

The OGM staff investigation indicates that the CW research program possesses the elements of a responsible safety program. There is an easily identifiable and detailed safety regulation, offices explicitly charged with enforcing safety, and evidence that these offices are actively engaged in enforcement efforts.

Unfortunately, despite these safety protections, the safety record for CSM research is far from comforting. For example, during 1986 and 1987, the Army's leading CW research facility, the CRDEC, was the subject of a massive probe which uncovered numerous safety problems there and throughout the

Aberdeen Proving Ground. The Army convened a formal board of investigation which conducted a year long study and filed 5 interim reports with more than 100 recommendations to correct deficiencies. When concluding its work in May 1987, the board indicated it had "identified a significant number of problems in the environmental, safety, and occupational health arenas," some of which would take years to correct. They included confusion over safety responsibilities, outdated and inadequate safety regulations, understaffed safety offices, an absence of safety inspections, inadequate training, and problems with storage and disposal of hazardous materials.

To illustrate the depth of the problem, here are some excerpts from the interim reports:

--"There are numerous structural deficiencies in some chemical laboratories, a number of which appear to be safety hazards. . . . [There is] a working laboratory with a gaping hole in the ceiling . . . [which has] existed for years."

--"Procedures for emergency medical response to chemical accidents, incidents or occurrences are not adequately established nor necessarily in line with the weight of expert medical opinion."

--"The facilities and present plans for the decontamination of chemical casualties are inadequate."

--"Insufficient attention is given to the inspection and maintenance of laboratories on the installation. . . . [T]he majority of the deficiencies are directly attributable to laboratory workers and their supervisors. In general, good laboratory practices are not being followed."

--During an inspection of the sanitary sewer system, "it was discovered that the system leg from Building E5100 had collapsed and the one from the Pilot Plant had numerous infiltration points."

--"Many laboratories are improperly using food-type refrigerators for the storage of chemicals . . . [which] constitutes a fire/explosive safety hazard."

--"Procedures for emergency communications in the Edgewood Area (EA) are inadequate. . . . Presently the EA phone switch is a mechanical relay type using technology that is about 20 years old. . . . [I]t often can take minutes to get a dial tone . . . . Laboratory personnel working with chemical agents . . . must have an absolutely reliable means of emergency communication."

--"The installation hazardous waste storage facility [HWSF] is unsuited for its current function and is in many ways inadequate. . . . [C]onditions . . . particularly in regard to personnel safety and hygiene, are deplorable. . . . There are no emergency decontamination facilities nor eye lavages . . . storage space for protective equipment . . . radio . . . [or] fire suppression system other than hand held extinquishers at each end of the HWSF buildings. . . . The training of HWSF personnel is inadequate."

The CRDEC is not the only CW research facility guilty of safety violations. Documents provided by the CRDEC and ICD safety offices indicate that a number of contractors, even those with long experience in CSM matters, have safety problems. Reports filed after safety inspections or accident drills repeatedly document contractor problems including, for example, an absence of required fire extinguishers, protective clothing, medical kits, decontamination solutions, employee training, and annual physical examinations; outdated safety plans; incomplete or missing safety inspection records; "extremely dirty" laboratory facilities; problems with emergency showers and eye washes; improper waste disposal practices; and storage problems. Poor performance by contractor employees during accident drills appears common. On at least five occasions, the Army has terminated contractors for failure to comply with the CSM rules.

The reasons for such safety violations and what can be done about them are pressing issues that warrant further examination by the OGM Subcommittee.

There are other problems with the CW safety program as well. For example, the periodic safety inspections of CW contractors are not always performed on a timely basis, especially by the ICD office. One extreme example is an ICD contractor which appears not to have been inspected in 4 years. A related problem is that actions taken by the offices to follow-up on safety violations are poorly documented. In many cases, it is difficult to determine whether the contractor remedied deficiencies cited in a particular report.

A third area of concern has to do with the CSM rules. While detailed in many areas, the CSM rules appear to have several safety gaps. For example, there appear to be no rules dealing with the issue of toxins and whether these substances constitute CSM. There are no rules requiring laboratories handling CSM to notify local officials, such as local fire marshalls, of the presence of CW agents in the community and of special fire-fighting needs that the laboratory may have. There are no rules about notifying neighbors and local communities of CBW facilities in their

midst. There appear to be no rules requiring the Army to perform a risk assessment of each new laboratory asking to handle CSM, in which the Army evaluates the laboratory's physical location -- its proximity to homes, schools and other community facilities -- in deciding whether CW research ought to be conducted at that site. There appear to be no rules requiring plans for evacuating surrounding communities in cases of emergency. These and possibly other deficiencies in the CSM rules merit a careful review.

In sum, while the safety protections for research involving CW agents are better than those for research involving BW agents, Congress should not rest easy. Attention needs to be paid to such issues as poor compliance with CSM safety rules, irregular safety inspections, and safety gaps in the CSM regulations. These and other safety problems in the CW research program need to be addressed.

Conclusion

The OGM staff recommends that hearings be held to examine the issues raised in this preliminary report, as well as issues that may be raised by the Environmental Impact Statement on the Biological Defense Program. Among the issues that merit review are:

(1) whether DOD should issue comprehensive safety regulations for research involving biological warfare agents and toxins and, if so, the substance of such regulations;

(2) whether DOD should create an office within the Biological Defense Program to monitor DOD laboratories and contractors for safe practices involving biological warfare agents and toxins;

(3) how to compel laboratories performing research with chemical warfare agents to improve the safety of their operations; and

(4) what improvements need to be made to the Chemical Surety Program and the safety offices monitoring laboratories that perform research with chemical warfare agents.

EXHIBIT A

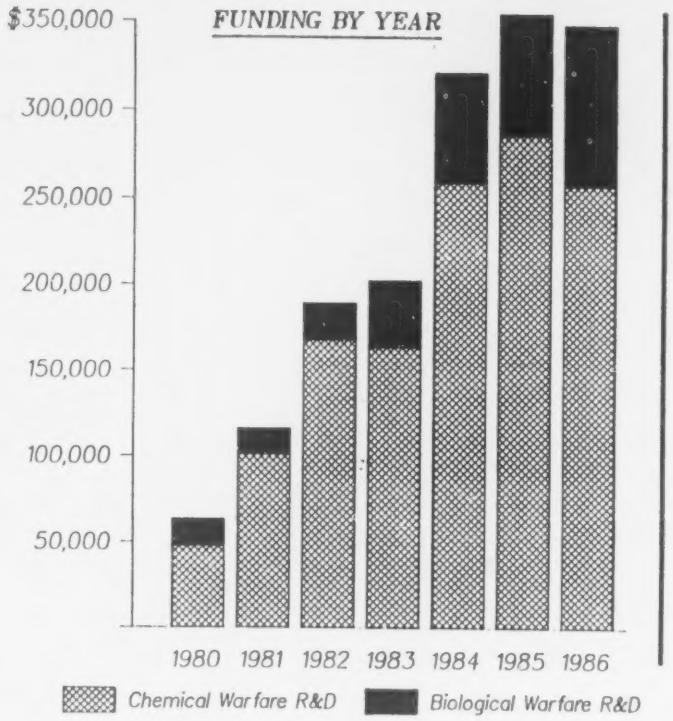
FEDERAL FUNDING OF
CHEMICAL AND BIOLOGICAL WARFARE RESEARCH

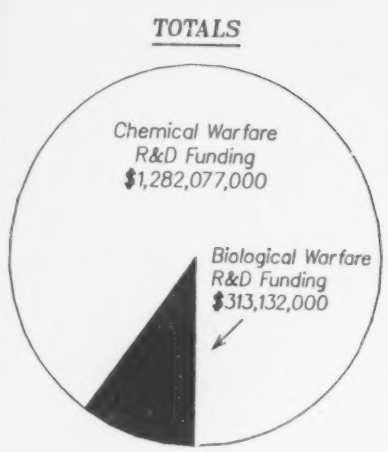
FISCAL YEAR	CHEMICAL WARFARE R&D	BIOLOGICAL WARFARE R&D	TOTAL ANNUAL CBW R&D
FY 80	$ 47,565,000	$ 16,026,000	$ 63,591,000
FY 81	101,048,000	15,096,000	116,144,000
FY 82	167,812,000	21,554,000	189,366,000
FY 83	163,371,000	38,802,000	202,173,000
FY 84	258,751,000	62,500,000	321,251,000
FY 85	285,977,000	68,528,000	354,505,000
FY 86	257,553,000	90,626,000	348,179,000
TOTAL:	$1,282,077,000	$ 313,132,000	$ 1,595,209,000

Prepared by Senate OGM Subcommittee Staff, May 1988. Funding amounts are taken from the Department of Defense Annual Reports on Chemical Warfare and Biological Defense Research Program Obligations, FY80-FY86. The figures indicate funding for research and development efforts and do not include funding for other types of CBW procurements, such as the purchase of weapons systems, defensive equipment or other items.

Figures do not include funding amounts for the Ordnance Program which has supported research of smoke, flame, incendiary, herbicide and riot control agents, and support equipment.

FEDERAL FUNDING OF CHEMICAL AND BIOLOGICAL WARFARE RESEARCH, 1980–1986





Total CBW R&D Funding
$1,595,209,000

Prepared By
OGM Subcommittee Staff

EXHIBIT B

EXHIBIT C

IN-HOUSE V. CONTRACTOR SPENDING FOR
CHEMICAL AND BIOLOGICAL WARFARE RESEARCH

	FUNDS FOR IN-HOUSE R&D	FUNDS FOR CONTRACTOR R&D	TOTAL ANNUAL CBW R&D	PERCENT ALLOCATED TO CONTRACTORS
FY 80	$ 37,310,000	$ 26,281,000	$ 63,591,000	41%
FY 81	61,232,000	54,912,000	116,144,000	47%
FY 82	82,104,000	107,262,000	189,366,000	57%
FY 83	82,102,000*	120,071,000*	202,173,000	59%
FY 84	115,300,000#	205,951,000#	321,251,000	64%
FY 85	120,128,000+	234,377,000+	354,505,000	66%
FY 86	130,591,000	217,588,000	348,179,000	62%
TOTAL:	$628,767,000	$966,442,000	$1,595,209,000	61%

Prepared by Senate CGW Subcommittee Staff, May 1988. Figures derived from Department of Defense Annual Reports on Chemical Warfare and Biological Defense Research Program Obligations, FY80-FY86. "In-House R&D" refers to CBW funds allocated to federal research facilities; "Contractor R&D" refers to CBW funds allocated by contract. The figures indicate funding for research and development efforts and do not include funding for other types of CBW procurements, such as the purchase of weapons systems, defensive equipment or other items. The figures do not include funding for the Ordnance Program which has supported research of smoke, flame, incendiary, herbicide and riot control agents, and support equipment.

* Includes $138,000 in Navy chemical warfare research funds which the FY83 Annual Report fails to designate as either in-house or contract funds. These funds have been allocated between the two categories using the ratio of in-house/contract spending for other Navy chemical warfare research funds during FY83; $81,000 is designated as in-house funds and $57,000 as contract funds.

Includes $1,401,000 in Air Force chemical warfare research funds which the FY84 Annual Report fails to designate as either in-house or contract funds. These funds have been allocated between the two categories using the ratio of in-house/contract spending for other Air Force chemical warfare research funds during FY84; $96,000 is designated as in-house funds and $1,305,000 as contract funds.

+ Includes $11,093,000 in Air Force chemical warfare research funds which the FY85 Annual Report fails to designate as either in-house or contract funds. These funds have been allocated between the two categories using the ratio of in-house/contract spending for other Air Force chemical warfare research funds during FY85; $937,000 is designated as in-house funds and $10,156,000 as contract funds.

Senator LEVIN. The NIH and Centers for Disease Control have classified biological toxins and viruses on a scale of 1 to 4. Classes 3 and 4 are the most inherently dangerous. Class 3 and 4 agents are so dangerous that they should be handled in a laboratory only under the strictest of conditions outlined by NIH and the Center for Disease Control, including a completely sealed environment isolated from other personnel and equipment.

In addition, because of the special dangers of mailing Class 3 and 4 agents, including inspection of humans, animals or plants with the potential for epidemic results, a special permit from the Department of Agriculture, the Public Health Service, or both, is required.

Fortunately at the present time only a small portion of the approximately 100 labs doing biological warfare research are working with Class 3 or 4 agents.

The Post Office, the Department of Transportation and the Public Health Service have published detailed regulations for packaging, labeling and mailing etiological agents. The Department of Agriculture also plays a major role in regulating the transportation of animal and plant pathogens. The Department of Transportation and Public Health Service rules apply whether the package is shipped by U.S. mail or private courier. Either way, the regulations apply.

These regulations have very specific directions for packaging etiological materials. There must be an inner and an outer container. The inner container must be waterproof and one from which the contents cannot penetrate to the outside. It also must have absorbent, cushioning materials, so that in case the vial in the inner container leaks, it can absorb the spill and keep the substance in the inner container. The outer container must also be nonpermeable.

It is the general assessment we can make, from talking with experts, that the regulations regarding packaging and labeling of these agents are substantially adequate. The problem is not with the regulations as written, as far as we can determine; the problem is assuring that facilities and individuals that are mailing these agents comply with the rules.

Here are some of the specific problems we have identified.

First, the enforcement system for these rules is inadequate. There are no requirements that etiological agents, particularly Class 3 and 4, be handled or packaged only by trained personnel. There is no oversight on the part of the Postal Service, the Department of Transportation or the Public Health Service of laboratory mailing procedures.

While the regulations are publicly available, and I assume widely circulated, there is no check on whether the laboratory personnel are aware of the regulations and complying with them. This is of increasing concern as more small laboratories become involved in biological warfare research.

For instance, at one major institution visited by Oversight Subcommittee staff, each lab researcher prepares and sends out his or her own mailings. There is no centralized shipping center which monitors outgoing mail to ensure compliance with appropriate regulations. The mailings at this particular institution are dropped in

an unguarded private courier box in a hallway, where they remain each day until a 5:00 p.m. pickup.

Even CDC has had its problems. In 1987 there was a lost mailing of a package containing a sample of infectious Crimean-Congo Hemorrhagic Fever, or CCHF, a Class 4 agent—that situation you mentioned in your opening statement.

The package was intended for USAMRIID. While USAMRIID did receive a package, the package did not contain the CCHF virus, but another substance instead.

I will submit for the record the documents produced to us by CDC detailing their search for the lost virus.

[The information follows. The attachments referred to are not printed.]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control

Memorandum

Date May 21, 1987

From Assistant Director for Laboratory Science
Division of Viral Diseases, CID

Subject Investigation of Missing Congo-Crimean Hemorrhagic Fever Virus Shipment
-Final Report-

To James O. Mason, M.D., Dr. P.H.
Director, CDC
Through Acting Director, CID
Through Director, DVD, CID

Summary of Incident

On Thursday May 7, 1987, the Special Pathogens Branch, Division of Viral Diseases (DVD), CID received a phone call from Dr. Douglas Watts, Virology Division, USAMRIID, Fort Detrick acknowledging that a shipment of frozen Congo-Crimean hemorrhagic fever (CCHF) virus from CDC had been received. The package had been mailed on dry ice from CDC on May 5 via Federal Express.

On Monday May 11 a second call from Dr. Watts informed Dr. Kevin DeCock, EIS Officer, Special Pathogens Branch, DVD that upon opening the container presumably holding the vials of virus culture, no CCHF virus was found but instead 2 small plastic bottles of rabies sorbent fluids were enclosed.

Dr. DeCock immediately reported this to Dr. Kenneth Herrmann, Assistant Director, DVD. An immediate search by Drs. Herrmann and DeCock of the packing and shipping room (Building 4, Room SB-2), including all freezers and refrigerators, was conducted in the event that the container of virus had not left the shipping room. This search failed to locate the container with the CCHF virus. Log records in the packing and shipping department indicated that on May 4 a shipment of rabies diagnostic reagents had been made to the Hawaii Department of Health. A call to Hawaii confirmed that the package with rabies reagents had been received on May 8, but that only a portion of the expected materials (i.e., rabies slides) was found in the package. Rabies sorbent fluids were expected but not received. No container with the CCHF virus was enclosed with the Hawaii shipment.

At that point the CCHF virus was declared missing. On May 12 AM Dr. McWilson Warren, Director OSS, CID, Dr. Fred Murphy, Director DVD, Dr. John Bennett, Acting Director, CID and Dr. Albert Balows, Assistant Director for Laboratory Science, CID were appraised of the incident and plans for an investigation and search for the missing virus were developed. A memorandum detailing the course of events related to the missing shipment was prepared by Dr. Herrmann on May 13, 1987, and the Office of Biosafety was asked to assist in evaluating the matter on May 14.

Investigation/Search Plan

On May 12 the following plan for further search and investigation was put into action:

1. Reconstruct events leading up to shipping the packages to Hawaii and to Ft. Detrick.

2. Survey by telephone all addressees to whom packages were shipped from the CDC shipping facility on May 5 or 6 (this survey was later expanded to include all shipments through May 11). A survey questionnaire (attached) was developed.

3. Review the procedures in the CDC packing and shipping activity.

   a. Use of temporary storage.
   b. Disposition of unidentified containers or materials.
   c. Record keeping.

4. Conduct a thorough in-house search of CDC for the missing container of virus.

   a. Mailroom
   b. DASH
   c. All freezers and refrigerators in CID (Clifton Rd, Chamblee, and Lawrenceville facilities).

5. Check U.S. Post Office "dead package" repository for the missing container.

Results of the Investigation

1. Events leading up to the shipments in question: On Monday, May 4 at approximately 1:00 PM the rabies reagents were delivered to Building 4, Room SB-2 by a technician from the CDC Lawrenceville facility Rabies Laboratory for packing and shipping to the Hawaii State Health Department. The reagents consisted of a packet of slide boxes wrapped in aluminum foil and 2-125 ml plastic bottles of adsorbing fluids (both clearly labeled). These were given directly to the person-in-charge of the packing room. The appropriate Request for Shipment form (CDC 57.7) (see attachment 1) and an address label accompanied the reagents. Later that same afternoon the package was completed and mailed to Hawaii. In retrospect it is apparent that only the slides were enclosed in that shipment. It is not known where the rabies sorbent fluids were stored at that time (a refrigerator, several -20°C freezers, and a dry ice storage chest exist in the packing room).

   The following morning, on May 5, technicians in the Special Pathogens Branch retrieved 2 vials (screw-capped cryogenic vials) of CCHF tissue culture passage fluid (approximately 1.0 ml each) from the freezer in the maximum containment laboratory (Building 9), sealed the vials (labeled only with laboratory ID numbers) in double heat-sealed plastic

bags, packed them with adsorbent material into a metal canister, and then placed the canister into an outer screw-capped fiber mailing container (3" diameter, 6 1/2" length). No identifying marks or labels were on the outer container. The freezer inventory control list confirms that the 2 vials of CCHF virus were removed on the date indicated. The container containing the frozen live virus was delivered on dry ice in late morning to Building 4, Room SB-2 by a technician from Special Pathogens Branch for the final packing and shipping by Federal Express to Dr. Watts at Fort Detrick. The Request for Shipment form (CDC 57.7) and an envelope containing a packing list to be enclosed with the shipment accompanied the container. The container and accompanying material was given directly to one of the two employees of the packing activity with verbal instructions that this was live virus and must be kept frozen. The deliverer left with the box containing dry ice on which she transported the container to Building 4.

It is unclear whether the container was placed temporarily in a freezer or dry ice chest in Building 4, SB-2 or was prepared immediately for shipment.

Sometime during early to mid-afternoon that same day the shipment box containing dry ice and presumably the container of CCHF virus was picked up from SB-2 by Mr. Charles O'Neal for Federal Express collection. The Federal Express pick-up routinely occurs about 3:00 PM each day.

2. Telephone survey of addressees: Based on the records in the Packing and Shipping activity, 98 packages were prepared and shipped from that facility between May 5 and 11. A detailed questionnaire was developed (see Attachment 2) and administered by phone to all addressees of these shipments. The objective of this survey was to determine as accurately as possible if the container with the CCHF virus might have inadvertently been included in an unrelated shipment prepared by the packing and shipping room staff. The results of this survey are summarized in table 1 (Attachment 3). All but four of the intended recipients of these shipments have been contacted, and in 92 of the 94 addressees from whom information was obtained, no evidence for the missing virus could be elicited. In 2 cases, the addressees claimed that the shipments addressed to them had not been received. Both were shipped at ambient temperature. The remaining four still awaiting confirmation of contents are all overseas shipments at ambient temperature. Follow-up efforts on these are continuing.

3. Review of packing and shipping procedures

   a. Occasionally materials to be shipped may be brought to the shipping room at a time when immediate attention to further packing and preparation for shipment may not be convenient. On such occasions, the materials may be stored temporarily (sometimes overnight) in the refrigerator or freezer in Room SB-2.

b. Unidentified containers or materials left or found in the shipping room area would routinely be sent to DASH for identification and disposition. Containers, mailers, etc, are reportedly not routinely discarded in the trash.

c. The packing and shipping room is not attended at all times.

d. The Request for Shipment form is the primary tracer and record of materials packed and shipped by the staff. Identifiers linking the Shipping form and the container of material to be shipped may be weak or absent.

4. Results of CDC in-house search for the missing container with virus:

a. Based on the possibility that someone in CID may have visited the shipping room on the days in question and returned to his/her laboratory with the missing container, a search of all CID laboratories, freezers and refrigerators was conducted on May 18-19 to rule out that possibility. An inspection of all freezers and refrigerators in CID (Clifton Road, Chamblee, and Lawrenceville facilities) failed to locate the missing container.

b. A thorough search of the CDC mailroom on May 18-19 failed to locate the missing container.

c. A thorough search of DASH was also conducted on May 18. All similar containers to the one missing were opened and contents checked. No evidence of the missing container was found.

5. Search of U.S Post Office "dead" mail repository: No evidence of a container resembling the description of the missing one has been found. The supervisor of the "dead package" repository indicates that if they suspect that an unidentified package may contain biologicals or specimen materials (they do not open such packages), they will routinely send them to CDC (i.e., DASH) to be opened and properly handled and/or disposed.

Potential Public Health Risk of this Incident

Congo-Crimean Hemorrhagic Fever (CCHF) virus belongs to the Bunyaviridae family of viruses. The agent is widespread throughout large areas of Asia and Africa, and in parts of Europe. The virus is transmitted primarily by tick bite, but nosocomial infections have been reported associated with exposure to blood of infected/viremic patients. Parenteral inoculation or exposure of skin or mucous membranes to high concentrations of virus is the likely route of nosocomial transmission of this agent. The virus is very difficult to grow in laboratory cell culture systems and maximum titers of under 10^5/ml are obtained. The virus is very labile and is rapidly rendered non-infectious at ambient temperature. Survival of cell culture grown virus at ambient temperature more than 24 hours is unlikely. Ingestion of the virus is unlikely to result in infection.

It is the considered conclusion of all of CDC's experts on this virus that the contents of this missing shipment do not pose a significant public health risk.

Recommendations and Conclusions

1. A substantial and thorough search has been made in an attempt to locate the missing virus shipment. This search failed to locate the shipment. Specifically no recipient of shipments during this period in question received the virus.

2. It is highly unlikely that, without constant frozen (-70°C or colder) storage, this material would still be infectious and pose a health risk to anyone finding and opening the container and vials. This lability of the virus represents a practical "fail-safe" element in this kind of shipment.

3. Dr. Joseph McCormick, Chief, Special Pathogens Branch, DVD, will brief Colonel David Huxsoll, Commander, USAMRIID, regarding the details of this episode.

4. A thorough review of the procedures for delivery of cultures and other materials to the CID shipping facility to ensure a controllable and manageable procedure has been initiated. This review is currently in progress and should be completed within the next 7-10 days. (An interim double check procedure is in place now.)

5. The CDC Incidents Panel should be requested to evaluate this unexplained laboratory incident, and submit its conclusions to the Director, CID and Director, CDC.

Kenneth L. Herrmann, M.D.

Attachments

cc: Dr. Balows
Dr. Warren
Dr. Taylor
Dr. Weisner
Dr. Murphy
Dr. Hopkins
Dr. Guinan

Senator LEVIN. CDC even went so far as to search the dead-letter section of the Post Office, without success. They finally concluded that the virus had been discarded by mistake in the trash. They concluded that there was no public health risk, because after three weeks at room temperature the virus would die and that infection during the three weeks was unlikely.

While this is the only instance we know about at CDC of a lost mailing, it illustrates the problems that can occur.

When the subcommittee asked USAMRIID for its report on this incident, they were informed that there is none and that CDC had no reports either.

In fact, CDC did have reports. We had CDC's reports in hand at the time of USAMRIID's statement to us. This suggests a coordination problem between CDC and USAMRIID, at least in this instance.

Second, once a package is in the mail system, there is no mechanism for determining compliance. Unless a package is visibly in violation of the regulations or is damaged or leaking, postal workers are required to leave them sealed. That makes sense. And even where there is a leak or visible damage, the CDC is supposed to be called to come in and handle the package.

But this means that as long as the outer package is in conformance, there is little likelihood that any noncompliance with the inner package will be caught. After several successful improper mailings a laboratory or company may conclude that they can get away with not meeting packaging requirements. There is no person responsible at each lab for carrying out the regulations and making sure they are complied with. When it hits the mail system, there is no mechanism for determining compliance either. Unless a package is visibly in violation of the regulations or is damaged or leaking, they are left sealed.

The problem is we don't know whether or not the package complies from a visible view of the outside, because the inside packaging could be a violation of the rules.

One question is, should we put into place a mechanism for random sampling of these packages, to be sure they comply both inside and outside?

Third, there is no requirement that, when using the Postal Service, all etiological agents be sent by registered mail.

While it appears that the Public Health Service regulations do require registered mail for Class 4 agents, there is not such a requirement that Class 1, 2 or 3 agents be sent by registered mail.

As I will mention, we believe they should be. If the Postal Service is going to continue to accept these packages, they should require registered mail for these as well as Class 4 agents.

Fourth, the reporting system for accidents involving the mailing or shipping of etiological agents is inadequate. The subcommittee has received Post Office and Department of Transportation records relating to accidents and incidents involving etiological agents.

The Department of Transportation is the agency responsible for overseeing the reporting of all accidents involving the transportation of hazardous materials, including the shipping of etiological agents. The Post Office also maintains its own records of incidents involving use of the postal system.

The Office of Technology Assessment, OTA, in a 1986 report entitled "Transportation of Hazardous Materials," found that the Federal Government's accident/incident reporting system for hazardous materials, including etiological materials, to be inadequate and in need of revision.

The Department of Transportation's records are incomplete, and the Post Office's accident and incident records, by their own admission, are informally kept. Right now there is no unified, integrated system for the reporting of such incidents.

I have been informed that witnesses from the Post Office will outline for you the training regimen that postal employees should receive for handling etiological mailings and the procedures they should follow in case of an accident or leakage from such packages.

Postal officials have informed the Oversight Subcommittee staff that its employees are given instructions concerning the handling of packages containing etiological agents as part of overall procedures governing the handling of hazardous materials.

We have also been told that postal employees also attend audiovisual presentations on the acceptance and handling of packages bearing special hazardous material labels.

They have also told us that these materials are to be segregated from other packages. In the event of an accident or leakage to a package containing etiological material, we have been told that postal employees are under instruction not to tamper with or open the package, but to call their supervisor or an inspector.

But these instructions were foreign to a mail handler the Senate Oversight Subcommittee staff has interviewed from the Frederick, Maryland, post office, who, I understand, will be testifying at today's hearing.

I was going to recount for you what he told my subcommittee staff, but I think it is more appropriate for him to speak for himself. I would like to stress, however, that the post office he is describing is not just any post office; it serves USAMRIID, the Defense Department's center for biological defensive warfare research. If special training or procedures are needed anywhere, it would be at post offices which are located near facilities which conduct biological defense-related research with viruses and toxins.

Apparently procedural changes are being instituted at the Frederick post office now, but according to what we were told, that is only after complaints by postal employees.

I might note for the record that the Government of Canada presently does not permit any etiological material to be shipped through its mail system. Canadian representatives told subcommittee staff that this prohibition was due to the opposition of the country's postal workers and the government's concern for the health and safety of its postal employees.

Still another problem that must be addressed is the not inconceivable situation in which disease-causing agents might be acquired through the mails for the purposes of terrorism or harm to humans.

An example is an incident that occurred at the ATCC. The ATCC, which I mentioned previously, does not generally sell dangerous etiological agents to private individuals. However, a company representative revealed one occasion when two people attempt-

ed to illicitly obtain through the mails a strain of botulism culture from the company.

Apparently the imposters used the letterhead of one of ATCC's regular customers to gain one shipment of a relatively harmless culture. Having received that, they forwarded a second false request asking that the potentially deadly botulism be mailed to a phony company address.

Meanwhile, ATCC had forwarded a receipt for the first order to its customer's normal billing address. When the customer disclaimed knowledge of either of the two orders, ATCC called in the FBI, which investigated and later apprehended the individuals involved.

Let me make some suggestions as to what can be done.

First of all, I think we ought to consider a random sampling requirement.

Secondly, I believe the labs should be required to have at least one person in the lab trained in the packaging of these materials, and that person should be responsible for properly complying with the regulations.

Third, one of the key points in the mailing of these substances goes beyond the requirements, that they freeze-dry the vast majority of materials they ship. We ought to consider requiring freeze-drying at least the most deadly agents by people who send these materials through the mail.

Next, the Postal Service should require, I believe, if they are going to continue to accept these packages, that these packages be sent by registered mail, so that if it is lost it can be traced more easily. Registered mail may be the custom now, but we don't know that it is always used. We are quite sure it is not always used. We believe it should be made mandatory if the Postal Service will continue to accept these mailings.

The Department of Transportation and the Postal Service should work together to have a uniform, comprehensive reporting system so all incidents involving these disease-causing agents are reported to one central location.

Finally, the area of penalties: we ought to take a look at the penalties and make sure they are in fact used as they are supposed to be used where there are violations where private couriers are used.

In the law there is a disincentive for a private courier to turn in a customer. I don't know how to get around that. Why would an express company being paid to handle a large volume of mail, that finds that a package is in violation of federal rules, turn that customer in for a possible civil fine or criminal penalty?

We are now checking the rules, and perhaps you or your staff or other Members may know the answer to this, as to whether there is a requirement that the private couriers report violations of these packaging rules. If not, there certainly ought to be, at least that requirement that the government be informed when packaging laws, that are so critical to public health, have been violated.

The bottom line problem, Mr. Chairman and other members of the subcommittees, is that we cannot give the public right now the assurance that they are entitled to, that our laws that provide for the safe packaging and mailing of these materials are being complied with. We don't know the level of compliance. We ought to be

in a position to give our public the kind of assurance that they are entitled to, that these disease-causing materials are properly packaged and mailed.

I commend you for holding these hearings.

Congresswoman Pelosi has been active in this. I am delighted that we are here together today to testify.

[The statement of Senator Levin follows:]

STATEMENT OF SENATOR CARL LEVIN

BEFORE THE

HOUSE SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION

OF THE POST OFFICE AND CIVIL SERVICE COMMITTEE

AND

HOUSE SUBCOMMITTEE ON RESEARCH AND DEVELOPMENT OF THE

ARMED SERVICES COMMITTEE

CONCERNING THE

TRANSPORTATION OF TOXIC SUBSTANCES THROUGH THE MAIL

June 23, 1988

Good afternoon, Mr. Chairman and Members of the Subcommittees. Thank you for inviting me to participate in this timely hearing. I commend you for your efforts in publicly addressing important questions pertaining to the mailing and shipping of biological warfare materials.

The Senate Subcommittee on Oversight of Government Management, which I chair, has been conducting an eighteen-month review of safety concerns associated with chemical and biological warfare--or CBW--research funded by the Department of Defense. Since you invited me to testify on use of the mails to transport biological materials and etiological or disease-causing agents, I will confine my remarks to the biological aspect of the CBW program.

As part of the Oversight Subcommittee's review, we have examined the mailing and shipping of etiological materials. Some of these etiological agents are harmless, others are not; some are deadly. The National Institute of Health or NIH and the Centers for Disease Control or CDC have classified biological toxins and viruses on a scale of 1 to 4 according to their hazard to human health. Classes 3 and 4 are those which are the most inherently dangerous. Some examples are: ebola virus, lassa fever, and certain types of encephalitis virus. Most Class 3 and Class 4 agents are so dangerous that they should be handled in a laboratory only under strict conditions outlined by NIH and CDC, including a completely sealed environment, isolated from other personnel and equipment. In addition, because of special dangers in mailing certain Class 3 and 4 agents (including infection of humans, animals or plants with the potential for lethal or epidemic results), a special permit from the Department of

Agriculture, the Public Health Service, or both, is required. Fortunately, at the present, only a small portion of the approximately 100 labs doing biological warfare research are working with Class 3 or 4 agents.

On May 11th of this year the Oversight Subcommittee's Majority Staff issued a preliminary report on the Defense Department's safety programs for chemical and biological warfare research. I'd like to submit a copy of that report for the record. This report revealed that federal funding of CBW-related research has increased by more than 500% since 1980. More than $1-1/2 billion dollars has been committed to CBW research during this decade. In addition, the Pentagon now contracts out CBW research projects to approximately 150 non-governmental labs across the United States. As mentioned earlier, approximately 100 of these labs are engaged in biological warfare research.

The dramatic increase in CBW funding, together with the proliferation of private companies and universities participating in biological warfare research under contract to the Department of Defense, has of necessity set the stage for increasing volumes of biological materials being shipped in the mails. It has also significantly increased the number of locations and personnel involved in the packaging, handling and opening of containers transporting biological warfare research agents.

4

Presently, the vast majority of the etiological agents are mailed or shipped in one of two ways -- through the United States Post Office or by private courier. Two key shipping points for the more dangerous, Class 3 and 4 agents are the U. S. Army Medical Research Institute for Infectious Diseases or USAMRIID ("You-Sam-Rid"), located at Fort Detrick, Maryland, and the federal Centers for Disease Control (CDC) in Atlanta, Georgia. USAMRIID is the center of the Army's biological de[illegible]se research program. CDC works with numerous disease-c[illegible]g viruses and toxins for a wide variety of purposes and plays a small role in certain aspects of the biological defense research program. Much of that research, say participants interviewed by the Subcommittee staff, is devoted to creating new vaccines to combat known disease-causing viruses and to devise new agents to neutralize biological weapons which could be employed against the United States by nations not adhering to the Biological Weapons Treaty.

A third, and perhaps the single largest shipper of biological agents in the United States, is the American Type Culture Collection or ATCC, of Rockville, Maryland. ATCC is a non-profit repository for a wide range of biological and etiological agents. It was created to help the scientific world acquire the cultures and specimens it needs to perform research work. In 1987, ATCC mailed approximately nine

hundred shipments of the most dangerous, Class 3 and 4 biological agents and toxins.

The Post Office, the Department of Transportation and the Public Health Service have published detailed regulations for packaging, labeling and mailing etiological agents. The Department of Agriculture also plays a major role in regulating the transportation of animal and plant pathogens. The Department of Transportation and Public Health Service rules apply whether the package is shipped by U.S. mail or private courier.

These regulations have very specific directions for packaging etiological materials. There must be an inner and an outer container. The inner container must be waterproof and one from which the contents cannot penetrate to the outside. It also must have absorbent, cushioning materials, so that in case the vial in the inner container leaks, it can absorb the spill and keep the substance in the inner container. The outer container must also be nonpermeable. Packages containing etiological agents must be clearly marked with a specially designed and universally-used biohazard label.

Many of the industry and scientific experts interviewed by Subcommittee staff agreed that the regulations regarding the packaging and labeling of etiological agents appear to be

substantially adequate as written. The problem is in assuring that the facilities and individuals mailing etiological agents are complying with these rules. Here are some of the specific problems we have identified.

First, the enforcement system for these rules is inadequate. There are no requirements that etiological agents -- particularly Class 3 and 4 -- be handled or packaged only by trained personnel. There is no oversight on the part of the Postal Service, the Department of Transportation, or the Public Health Service of laboratory mailing procedures. While the regulations are publicly available, and I assume widely circulated, there is no check on whether the laboratory personnel are aware of the regulations and complying with them. This is of increasing concern as more small laboratories become involved in biological warfare research. For instance, at one major institution visited by Oversight Subcommittee staff, each lab researcher prepares and sends out his or her own mailings; there is no centralized shipping center which monitors outgoing mail to ensure compliance with appropriate regulations. The mailings at this particular institution are dropped in an unguarded private courier box in a hallway where they remain each day until a 5:00 P. M. pickup.

Even CDC has had its problems. In 1987 there was a lost mailing of a package containing a sample of infectious

Crimean-Congo Hemorrhagic Fever (CCHF), a Class 4 agent. The package was intended for USAMRIID. While USAMRIID did receive a package, the package did not contain the CCHF virus, but another substance instead. I will submit for the record the documents produced to us by CDC detailing their search for the lost virus. CDC even went so far as to search the dead-letter section of the Post Office, without success. They finally concluded that the virus had been discarded by mistake in the trash. They concluded that there was no public health risk, because after three weeks at room temperature the virus would die and that infection during during the three weeks was unlikely. While this is the only instance we know about at CDC of a lost mailing, it illustrates the problems that can occur. When the Subcommittee staff asked USAMRIID for its reports on this incident, they were informed that there none and that CDC had no reports, either. I have a copy of this response for the record. In fact CDC did have reports -- we had CDC's reports in hand at the time of USAMRIID's statement to us. This suggests a coordination problem between CDC and USAMRIID at least in this instance.

Second, once a package is in the mail system, there is no mechanism for determining compliance. Unless a package is visibly in violation of the regulations or is damaged or leaking, postal workers are required to leave them sealed. That makes sense. And even where there is a leak or visible

damage, the CDC is supposed to be called to come in and handle the package. But this means that as long as the outer package is in conformance, there is little likelihood that any noncompliance with the inner package will be caught. After several successful improper mailings, a laboratory or company may conclude that they can get away with not meeting packaging requirements.

Third, there is no requirement that when using the Postal Service, all etiological agents be sent by registered mail. While it appears that the Public Health Service regulations do require registered mail for Class 4 agents, there is not such a requirement that Class 1, 2, or 3 agents be sent by registered mail. We were told that if such a package, properly wrapped and labelled on the outside, were dropped into a corner mailbox, there would be nothing to prevent that package from being mailed, unless a postal worker became alarmed. Thus, it would be possible for a Class 3 agent to be mailed through the normal channels.

Fourth, the reporting system for accidents involving the mailing or shipping of etiological agents is inadequate. The Subcommittee has received Post Office and Department of Transportation records relating to accidents and incidents involving etiological agents. The Department of Transportation is the agency responsible for overseeing the reporting of all accidents involving the transportation of

hazardous materials, including the shipping of etiological agents. The Post Office also maintains its own records of incidents involving use of the postal system.

The Office of Technology Assessment (OTA) in a 1986 report entitled "Transportation of Hazardous Materials" found that the federal government's accident/incident reporting system for hazardous materials, including etiological materials, to be inadequate and in need of revision. The Department of Transportation's records are incomplete, and the Post Office's accident and incident records, by their own admission, are informally kept. Right now, there is no unified, integrated system for the reporting of such incidents.

I've been informed that witnesses from the Post Office will outline for you the training regimen that postal employees should receive for handling etiological mailings and the procedures they should follow in case of an accident or leakage from such packages. Postal officials have informed the Oversight Subcommittee staff that its employees are given instructions concerning the handling of packages containing etioligical agents as part of overall procedures governing the handling of hazardous materials. We've also been told that postal employees also attend an audio-visual presentations on the acceptance and handling of packages bearing special hazardous material labels. They have also

told us that these materials are to be segregated from other packages. In the event of an accident or leakage to a package containing etiological material, we've been told that postal employees are under instruction not to tamper with or open the package, but to call their supervisor or an inspector.

But these instructions were foreign to a mail handler the Senate Oversight Subcommittee staff has interviewed from the Frederick, Maryland, Post Office, who, I understand, will be testifying at today's hearing. I was going to recount for you what he told my subcommittee staff, but I think it's more appropriate for him to speak for himself. I would like to stress, however, that the post office he is describing is not just any post office; it serves USAMRIID, the Defense Department's center for biological defensive weapons research. If special training or procedures are needed anywhere, it would be at post offices which are located near facilities which conduct biological defense-related research with viruses and toxins.

Apparently procedural changes are being instituted at the Frederick Post Office, now, but according to what we were told, that is only after complaints by postal employees. I might note for the record that the government of Canada presently does not permit any etiological material to be shipped through its mail system. Canadian representatives

told Subcommittee staff that this prohibition was due to the opposition of the country's postal workers, and the government's concern for the health and safety of its postal employees.

Still another problem that must be addressed is the not inconceivable situation in which disease-causing agents might be acquired through the mails for the purposes of terrorism or harm to humans. An example is an incident that occurred at the ATCC. The ATCC, which I mentioned previously, does not generally sell dangerous etiological agents to private individuals. However, a company representative revealed one occasion when two people attempted to illictly obtain through the mails a strain of botulism culture from the company. Apparently the imposters used the the letterhead of one of ATCC's regular customers to gain one shipment of a relatively harmless culture. Having received that, they forwarded a second, false request asking that the potentially deadly botulism be mailed to a phony company address. Meanwhile, ATCC had forwarded a receipt for the first order to its customer's normal billing address. When the customer disclaimed knowledge of either of the two orders, ATCC called in the FBI, which investigated and later apprehended the individuals involved.

The question we now must turn to is what can and should be done. I think the answer to that question requires

careful consideration by your subcommittees and by ours on the Senate side. I have a few suggestions, based on what we've learned.

First, a system of random sampling should be instituted by the Postal Service and private carriers, to determine the extent to which the packaging regulations are being followed. If a problem is evident, then the sampling should be increased. Any improperly packaged materials should be returned, and investigations should be conducted to determine whether the failure to comply with the regulations was intentional or negligent.

Second, laboratories should be required to have at least one person or one office that is trained in the packaging and mailing of etiological materials. All such packages should be prepared and received through that one person or office.

Third, the Subcommittee staff learned that ATCC goes beyond the requirements in the federal regulations and freeze dries the vast majority of the materials which it ships. Consideration should be given to requiring freeze drying of at least the most deadly agents.

Fourth, the Postal Service should require, at a minimum, that all etiological agents to be sent by registered

mail if it is going to continue to accept these packages. Should a package be lost at least it can be traced if it is registered. While registered mail appears to be the custom and practice, it should be made mandatory.

Fifth, safeguards must be developed to prevent unauthorized personnel from obtaining potentially harmful biological warfare agents being shipped in the mails.

Sixth, the Department of Transportation and the Postal Service should work together to develop a uniform and comprehensive reporting system for accidents and incidents involving etiological agents.

Seventh, violations of the packaging requirements, whether the Postal Service or private couriers are used, should carry stiff penalties. If the violation is a negligent one, the penalty should be a civil or administrative fine. If the violation is intentional, the sanction should include criminal penalties. My subcommittee staff will be examining the sanctions currently in effect to assess the extent to which they should be increased and expanded.

Mr. Chairman, again, I commend you for holding these important hearings and for allowing me to share with you the information obtained by my Subcommittee staff. We would be happy to work with the Members and staff of your subcommittees in identifying any additional problem areas and possible solutions.

Mr. McCLOSKEY. Thank you very much, Senator, for an excellent statement. I appreciate, again, your leadership.

Would you have a few more minutes so we can hear from Mrs. Pelosi and perhaps treat you as an informal panel?

Senator LEVIN. I did have a commitment, but perhaps I can change it. I checked with Congresswoman Pelosi and she assured me it would be all right.

Mr. McCLOSKEY. I have one or two brief questions and perhaps other members may have questions.

On a related but very important area, from your two years or more experience in this, would you say there is any significance or substantive possibility that any of these organisms can or could readily spread?

As you know, when DOD representatives testify, they will show you the packaging and they will show you the dry cloth and three containers and say not even an atomic explosion can pop one of these open. We have had testimony to the effect that these things have popped open all the time in transit. They say it will dry up and die on the spot.

What do you think about that?

Senator LEVIN. We don't think that is accurate. They have a life expectancy that varies, depending on the agent, and they are very dangerous. These are some of the most dangerous substances known to human beings.

Mr. McCLOSKEY. In my briefing yesterday DOD made a definite point that they did not mail—I guess at this time; I don't know how long—but at this time they claim they do not mail any etiologic substances, that they use private couriers. That is a different, but related, set of issues. It was said that they received these materials all the time.

Would you not say DOD should have some safety and jurisdictional concerns for these materials coming in from agencies they contract with, as well as what they send out by mail?

Senator LEVIN. Whether they use the Postal Service or private courier, we don't think that should make any difference. The public is entitled to the same assurance, whether it is the Postal Service or private couriers.

Mr. McCLOSKEY. Governor Brennan.

Mr. BRENNAN. Thank you, Mr. Chairman. I likewise want to commend you for holding this hearing on something that is timely and of serious concern, particularly with people who work in the Postal Department, with respect to the matter of dealing with potentially lethal materials through the mail.

The potential was recently brought to my attention by a group of postal workers in my District. An incident occurred in the Portland, Maine, post office where blood spilled and leaked through the protective packaging. A postal worker unaware of the spill got blood on his hands.

Accidents like these are not only dangerous to the postal workers, but also to the general public. It is my understanding there have been two such incidents in the Portland, Maine, post office this year.

I would like to express my concern about current postal practices and urge the Postal Service to review current mailing practices to

insure the safety and the well-being of postal workers as well as the general public.

So I do think it is very timely that you are holding these hearings. It is something that is certainly of serious concern to a good number of people.

Thank you very much.

Mr. McCLOSKEY. Are there any other questions?

Mrs. BOXER. I have no questions, other than to thank the Senator for taking the leadership.

I will hold my comments until after Congresswoman Pelosi's testimony.

Mr. McCLOSKEY. Thank you very much, Senator. We appreciate your appearance.

Senator LEVIN. I also want to thank the Congresswoman.

Mr. McCLOSKEY. We are glad to have you here today, Congresswoman Pelosi.

Ms. PELOSI. Thank you, Mr. Chairman.

STATEMENT OF HON. NANCY PELOSI, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Ms. PELOSI. I also want to commend the subcommittees for holding this hearing today. I appreciate the opportunity to come before you to testify on a project which poses a grave danger to our population.

I was first made aware of this danger by California Attorney General John Van de Kamp, who I understand submitted a statement for the record, as well.

The U.S. Army plans to send biological toxins and etiologic agents to its proposed Biological Aerosol Test Facility, BATF, at the Dugway Proving Ground in Utah via the U.S. mail. These dangerous biological agents will be sent from over 100 research facilities nationwide to the Dugway facility by registered mail, subject to HHS and Postal Service regulations. I believe that this proposal will expose postal workers and the general public to an unacceptable health risk.

In January of this year, the Department of the Army completed a Draft Environmental Impact Statement, DEIS, for the BATF project. The DEIS fails to discuss fully the potential risk to postal employees and the general public which might result from the accidental release of a biological organism or its toxin during shipping. In addition, alternative shipping methods are not discussed in the Army's DEIS.

The Army goes to great lengths to describe the safety precautions that will be put into place at the Dugway facility to protect laboratory workers and the surrounding environment from exposure to these harmful organisms.

Without commenting on the adequacy of these safeguards, I would like to point out the glaring lack of concern with shipping safeguards. In a statement of over 200 pages, less than one page is devoted to shipping procedures.

Biological organisms that could be used as weapons in an armed conflict exhibit characteristics which, by definition, present grave dangers to the public. To be effective in warfare, such organisms

must be highly infectious and virulent; they must be able to survive adverse environmental conditions; and they must be able to spread through the air.

The Army's DEIS states that the biological agents which will be used at Dugway were chosen "because they pose the greatest challenge to safety and containment."

These include, but are not limited to, bacillus anthracis and coxiella burnetii. Bacillus anthracis causes anthrax. If inhaled or ingested, anthrax is often fatal to humans. Anthrax spores are very resistant to environmental conditions and may persist in the soil for centuries. Ground water contamination is a serious potential problem. Coxiella burnetii causes Q fever, an acute illness which resembles pneumonia. It is highly infectious, only one organism can cause infection if inhaled, and it is easily transmitted through the air.

In addition, the toxins, or poisonous byproducts of these organisms, are hazardous. Exposure to the toxin of the anthrax bacteria is extremely serious and can cause death. This is also true of the botulism toxin.

The U.S. Postal Service does an outstanding job in its handling of over 508 million pieces of mail daily. In 1987 the Service handled over 173,000 pieces of registered mail daily and, of these, 2,816 items, or less than 2 percent, were reported lost or damaged. While this percentage may be adequate for ordinary mail, it is unacceptable for packages which contain highly toxic materials such as those which I have cited.

On June 2 I sent a letter signed by eighteen of my colleagues to Secretary of Defense Carlucci, requesting him to develop alternative plans for the shipment of biological toxins in light of the lethal nature of these materials. I have not yet received a reply from Mr. Carlucci, but anticipate that I will soon.

I understand that the U.S. Postal Service will soon announce new regulations aimed at preventing the mailing of these dangerous biological agents. Should these regulations not be adequate, I am prepared to introduce legislation to prohibit using the U.S. mail for this purpose.

I urge the subcommittee to review the regulatory changes carefully and I look forward to working with my distinguished colleagues to ensure the safety of postal workers and the public.

I would like to submit the letter to Secretary Carlucci for the record.

Mr. MCCLOSKEY. Without objection.

[The letter follows:]

Congress of the United States
House of Representatives
Washington, DC 20515

June 2, 1988

Honorable Frank Carlucci
Secretary of Defense
The Pentagon
Washington, D.C. 20301-1155

Dear Secretary Carlucci:

We wish to express our concern over a plan by the U.S. Army to send biological toxins by registered mail. These toxins would be transported via the U.S. Postal Service from research centers located throughout the country to the proposed counter-biological warfare testing center at Dugway, Utah.

We believe that the shipment of dangerous toxins by registered mail could expose the public to an unacceptable level of risk. The loss or mishandling of these materials, as well as the possibility of their deliberate misuse, could result in catastrophe.

We request that you develop alternative plans for the safer shipment of biological toxins in light of the extremely lethal nature of these materials.

We look forward to your reply.

Sincerely,

Nancy Pelosi
NANCY PELOSI, M.C.

Don Edwards
DON EDWARDS, M.C.

Mike Lowry
MIKE LOWRY, M.C.

Ronald V. Dellums
RONALD V. DELLUMS, M.C.

Wayne Owens
WAYNE OWENS, M.C.

Connie Morella
CONSTANCE A. MORELLA, M.C.

JIM JONTZ, M.C.

FORTNEY H. (PETE) STARK, M.C.

JIM BATES, M. C.

JOE KOLTER, M.C.

BYRON L. DORGAN, M.C.

ROBERT J. MRAZEK, M.C.

CHESTER G. ATKINS, M.C.

LAWRENCE J. SMITH, M.C.

ROBERT T. MATSUI, M.C.

NORMAN Y. MINETA, M.C.

CHARLES B. RANGEL, M.C.

SAMUEL S. STRATTON, M.C.

MARY ROSE OAKAR, M.C.

Mr. McCLOSKEY. Mrs. Boxer?

Mrs. BOXER. Thank you.

I, too, want to thank you for these hearings. I wanted to thank you for working with me to get Chairman Aspin to participate in these joint hearings because I think it is important that the Armed Services Committee be informed of this all the way. You have been very helpful.

Congresswoman Pelosi has been very helpful on this issue, for which I thank her. We share concern on this issue. Both of us were briefed by Attorney General Van de Kamp. I have his testimony here, which I would like to place in the record.

Mr. McCLOSKEY. Fine.

[The information follows:]

1515 K Street, Suite 600
P. O. Box 944255
Sacramento, California 94244-2550
(916) 324-5437

3580 Wilshire Boulevard, Suite 800
Los Angeles, California 90010
(213) 736-2273

State of California

Office of the Attorney General

John K. Van de Kamp
Attorney General

June 20, 1988

The Honorable Frank McCloskey
U.S. House of Representatives
Subcommittee on Postal Personnel and Modernization
603 House Office Building Annex 1
Washington, D.C. 20515

Dear Congressman McCloskey:

Re: **Transport of Biological Toxins**

John K. Van de Kamp, Attorney General of the State of California, submits this testimony pursuant to his powers under the California Constitution and the California Government Code to protect the environment of California. This testimony is not offered on behalf of any other State agency or official.

The practice of shipping biological toxins through the mail first came to my attention in early April of this year. I was shocked to learn that the Army planned to ship bacteria and viruses capable of causing debilitating or fatal diseases or reactions through the registered mail. These toxins are to be used for testing at the Biological Aerosol Testing Facility proposed to be constructed at the Dugway Proving Ground in Utah. The Environmental Impact Statement for the facility explains that some of the agents are infectious at extremely low exposures, including Q virus, botulism and anthrax. In addition, VEE (Venezuelan Equine Encephalitis) is not indigenous to North America; it therefore could have serious ecological repercussions if released because the local flora and fauna have no known natural resistance.

Given the danger of these substances, the testing facility features elaborate protective precautions. These include containment facilities such as biological safety containment cabinets, sequential air filtration systems for exhaust air, and deactivation of liquid and solid waste. All these devices are equipped with emergency backup systems. Other safety factors include frequent checks on the integrity of the control systems, automatic monitoring systems fitted with alarms and the conduct of tests during daylight hours only. The Utah environment also

provides a natural barrier; the hot, dry climate at Dugway is antithetical to the survival of many of the organisms involved. In addition, laboratory personnel will be comprehensively trained and immunized.

We are very concerned about the possible danger of leakage during the shipping process, when the protective measures provided at Dugway are not present. In our comments on the EIS, we first requested that the Army provide information as to the planned shipping routes of the biological agents. The EIS is totally silent on this point. We have recently submitted a Freedom of Information Act request to the Army, asking for the release of records indicating where such shipments of biological agents have come from in the past, and where they will come from in the future.

In addition, we have asked the Army to discuss the possible effects of a release during shipping through the U.S. mail. Pursuant to the National Environmental Protection Act, and out of concern for the health and safety of the general public, we also believe that the Army must consider alternative shipping methods. For example, the use of appropriately trained Army personnel, using military transport that is appropriately equipped, could be considered. Alternatively, special courier services who are aware of what they are carrying and are prepared to deal with an accident might also be considered.

I am aware that the possibility of a release that actually infects people or animals is probably a small one. Nonetheless, it is my understanding that there have been several reported incidents in which packages containing infectious agents have leaked. This is an issue of great concern to both the public and postal workers. These workers must handle potentially dangerous biological material shipped by the Army and medical laboratories throughout the country.

I strongly urge Congress to adopt regulations according postal workers and the public greater protection against the hazards of shipping biological toxins through the U.S. mail. In particular, I believe the feasibility of alternative shipping measures should be evaluated. In any case, Congress should seriously consider the wisdom of using the U.S. mail to ship materials deemed potential biological warfare agents.

Very truly yours,

JOHN K. VAN DE KAMP
Attorney General

Enclosure

JOHN K. VAN DE KAMP
Attorney General

State of California
DEPARTMENT OF JUSTICE

3580 WILSHIRE BOULEVARD, ROOM 500
LOS ANGELES 90010
(213) 736-2304

May 13, 1988

U.S. Army Dugway Proving Ground
Attention: STEDP-PA
Dugway, Utah 84022-5000

To Whom It May Concern:

Re: Draft EIS on Biological Aerosol Test Facility

These comments on the Draft EIS regarding the Biological Aerosol Testing Facility ("BATF") proposed to be constructed at the Dugway Proving Grounds are submitted on behalf of John K. Van de Kamp, Attorney General of the State of California, acting pursuant to his powers under the California Constitution and the California Government Code to protect the environment of California and the health and welfare of its citizens. These comments are not offered on behalf of any other State agency or official. The comments are filed pursuant to the notice of April 19, 1988, 53 Fed. Reg. 12803, extending the comment period on the DEIR.

We will confine our comments to one topic discussed in the Draft EIS: the shipment of biological agents through the open mails, using the Postal Service's registered mail (DEIS, page D-27). In this context, we wish to request additional information from the Army. Specifically, we would like to know whether any of the biological agents to be sent to the BATF will be intentionally shipped from or through the State of California. The DEIS is totally silent on this point, giving no information as the origin or route of shipment of any of the materials that will be sent to Dugway in connection with this proposed project. We are very concerned about the possibility that these shipments may be routed through California, and will, if necessary, follow these comments with a request pursuant to the Freedom of Information Act that the Army provide this routing information to us. Could you please advise us as to whether a FOIA request will be necessary, or whether the Army will release the information to us without one?

We will now address the topic of shipping biological agents through the Postal Service in the manner described in the DEIS. Briefly put, we are concerned about the possibility of a release of harmful bacteria or viruses during the shipping process, a possibility that is neither considered nor discussed in the DEIR. We are aware that the DEIS takes the position that no release is possible at the BATF itself, and therefore does not analyze or disclose the possible environmental effects of such a release. Since the Dugway Proving Grounds are not within our jurisdiction,

we express no opinion on this position. However, it seems plain to us that the types of controls, equipment, training and procedures that the Army cites to support this position do not exist in the shipping process.

The DEIS states that no release is possible at the BATF because of the elaborate containment facilities to be used in the BATF, the training and inoculation of BATF personnel, the comprehensive containment procedures that will be used (DEIS, sections G.3 and G.4), and because of the hot, dry climate at Dugway (which is antithetical to the survival of many of the organisms involved, DEIS, App.VII, sections 3.1.1 to 3.1.5) and its isolation (DEIS, section D.6.2). Even if it is assumed that these factors would prevent a release of biological agents at the BATF, the Army cannot be sure that any of these factors would be present during shipping, and it can be quite sure that most of them would be absent. For example, Postal Service facilities and vehicles do not have the elaborate containment equipment of a BATF, and Postal Service employees will not be trained to deal with a release of these agents. Indeed, because the warning labels will be placed on the hermetically sealed can, inside the shipping box where the warnings can only be seen if the package has been partially opened, Postal Service employees will not even know that they ought to be taking any extra precautions. Certainly, they will not have the training or equipment to deal with a release of toxins that may cause anaphylactic shock, or a release of VEE virus or other viruses or bacteria. Further, the temperature, time of day, and humidity prevailing at the time of any accidental release in shipping may be those that favor survival of the agents released, allowing them to live and possibly infect people exposed to them.

We believe that the accidental release of biological agents during shipments is a reasonably foreseeable event, and that therefore the EIS should analyze the possible environmental effects of such a release and reveal them to the public. Certainly, such a possibility is within the "rule of reason" cited in 40 CFR 1502.22. An automobile accident involving a Postal Service vehicle, a fire at a Postal Service facility, carelessness on the part of mail handlers, misdirection of mail and other mishaps are a part of everyday life, and are not only reasonably but easily foreseeable. We therefore believe that the National Environmental Policy Act requires the Army to address these possibilities, and to discuss fully the possible effects of a release during shipping, where containment, specialized personnel training, and other safeguards are absent.

The DEIS states that federal regulations governing shipment of biological agents will be complied with and necessary permits obtained. While we commend the Army for following the applicable rules and regulations, nevertheless, this is not a substitute for

compliance with NEPA. Case law clearly and repeatedly has held that compliance with the regulations of other federal agencies does not substitute for or excuse compliance with the NEPA full disclosure requirements. See The Steamboaters v. FERC, 759 F.2d 1382 (9th Cir. 1985); Oregon Environmental Council v. Kunzman, 714 F.2d 901 (9th Cir. 1983). Similarly, in this case, even though the Army has complied with appropriate regulations and obtained required permits, it must still analyze and reveal the possible environmental consequences of utilizing a shipping method that may result in accidental releases.

In addition, the EIS must address the alternatives to use of the Postal Service to ship these materials. No discussion of alternatives to this facet of the project occurs in the DEIS, even though this may well be the one area of the project most likely to cause an unintentional release of biological agents. The consideration of alternatives is the heart of the EIS process, and certainly here the Army is legally required to consider alternatives to this nonsecure method of shipping. See 42 USC 4332(E); Environmental Defense Fund, Inc. v. Corps of Engineers, 492 F.2d 1123 (5th Cir. 1974); Natural Resources Defense Council v. Calloway, 524 F.2d 79 (2d Cir. 1975). For example, the use of Army personnel, appropriately trained, using military transport that is appropriately equipped, could be considered. Special courier services who are aware of what they are carrying and are prepared to deal with an accident might also be considered. We are confident that the Army can devise and evaluate alternative shipping methods. We believe they are required to do so.

We are aware that the possibility of a release that actually infects people or animals is probably a small one. Nevertheless, the danger posed if such a release does occur is a substantial one. The DEIS states that some of the biological agents to be shipped to and tested at Dugway are infectious at very low rates of exposure (DEIS, App.VII, sections 2.2.2, 2.2.3), and could have serious consequences if released (see discussion of VEE virus at App. VII, section 3.5.1). We are naturally very concerned about any possible danger of release in California or at its borders, and are concerned about the utter lack of information and notice California will have about these dangers. When the risk of release of biological agents is presented by every Postal Service truck or plane, and when warnings are on labels that are unlikely to be easily discovered by firefighting or other emergency personnel responding to an accident, the State has little means of protecting its citizens. We need the fullest possible information on this danger, and we look to the Army to provide it, as required, through the NEPA process. We therefore urge the Army to include this analysis in the final EIS.

We thank you for your courtesy and attention to these comments. We also request that you send us a copy of the Final EIS when it is issued.

Very Truly Yours,

JOHN K. VAN DE KAMP
Attorney General

Susan L. Durbin

SUSAN L. DURBIN
Deputy Attorney General

Mrs. BOXER. I would like to summarize my opening statement and place the complete one in the record.

Mr. Chairman, this is a very serious issue, as Congresswoman Pelosi and Senator Levin have pointed out. This situation was brought to my attention and to Ms. Pelosi's attention, as I said before, by our very fine Attorney General. He alerted us to the fact that California is in all likelihood greatly affected by the routing of these dangerous substances through the mail.

I use the term "in all likelihood," Mr. Chairman, and I think this is important, because we do not know exactly what route these shipments will take or from where they originate. I hope we will learn at this hearing.

We know they are going to the Dugway, Utah, testing facility. We believe several of the biological research centers are in California and we have to assume they will be receiving such viruses through the mail.

It is a serious matter and, as Ms. Pelosi pointed out, the Dugway facility is fitted quite carefully for the handling of dangerous bacteria, but the average postal worker or UPS employee is certainly not privileged to have that type of protection.

As a member of the Armed Services Committee, I understand DOD has been sending such packages for some time. They claim there have been no major incidents to date. I believe them. I believe they are saying it the way it is. But I also have to believe that as we continue on this trail and we are looking at more and more powerful and potent agents, as my colleague has described to us, it is time to take a very hard look at old practices.

You cannot stand still; you have to stay ahead of the curve. Because we may not have had a disaster does not mean we will not have one.

I want to mention what my colleague said about the potency of these agents. I am told that some of the viruses passing through our mail can cause bacterial diseases like anthrax, which can be acquired through just a scratch—just a scratch could cause this problem and kill a person or result in encephalitis, which causes inflammation of the brain, for which no good treatment exists—or Q fever, which causes pneumonia; you can get that from the air. These viruses are intended for warfare, intended to kill people.

We cannot say we have had no problems so we will put another wrapper around them. That is not going to work. I would urge the Army to look into alternatives. I think Senator Levin has laid those out, and Congresswoman Pelosi has talked about potential legislation. I would hope we can take care of those without having to go through that process. I would like to have a good public hearing and come up with some solutions.

Mr. Chairman, I thank you for your keen interest in this very important project.

Mr. MCCLOSKEY. Thank you.

[The statement of Mrs. Boxer follows:]

PREPARED STATEMENT OF HON. BARBARA BOXER

I want to thank the chairman for holding this joint hearing on this very serious issue.

The fact that toxins being developed for use as biological warfare agents were being sent through the regular mail or with private delivery services such as Federal Express was first brought to my attention by the Attorney General of the State of California, John Van de Kamp. I would like to submit Mr. Van de Kamp's testimony for the record.

He alerted me to the fact that California is in all likelihood greatly affected by the routing of these dangerous substances through the mail. I say "all likelihood" because we do not know exactly what route shipments take or from where they originate. The DEIS prepared for the Dugway testing facility is silent on the subject of the transportation of biological agents to and from Dugway, aside from saying that shipping requirements are being met. However, I do know that seven of the Army's 103 authorized biological research centers are in California, so I presume that they have in fact been receiving and sending such viruses and biological agents in the mail or from private couriers unequipped for transporting such material.

This is a very serious matter. While it is clear that the Dugway facility is properly fitted for the handling of dangerous and deadly bacteria, it is obvious that the average postal or UPS employee or postal customer is not protected by the same facilities or trained to deal with possible leaks. I am a member of the Armed Services Committee, and I understand that the DoD has been sending such packages for some time, with no major incidents of disastrous exposure to date.

However, I also understand that there have been recorded instances of packages coming undone. My concern is that we must stay ahead of the curve. One hears talk of new formulations and of the development of new, powerful bacterial agents for warfare. With such developments must come corresponding improvements in the handling and transportation of those agents. As the risk of the possible consequences grow, our policies must change to continue to ensure the safety of the average citizen who might be accidentally exposed. And as I said, we know it can happen.

The viruses we are talking about are extremely infectious and can be deadly, if not debilitating. I am told that some of the viruses passing through our mail can cause bacterial diseases like anthrax, which can be acquired through just a scratch and kills people, or encephalitis, which causes inflammation of the brain and for which no good treatment exists, or the Q Fever, which causes pneumonia and you can get from contaminated air. The bottom line is that these viruses are intended for warfare, they are intended to kill people.

I urge the Army to look into alternatives to shipping through the regular mail or with private mail delivery services, and I look forward to hearing from our witnesses today how we can best protect the public.

Mr. MCCLOSKEY. Mr. McCurdy?

Mr. MCCURDY. I have no questions.

Mr. MCCLOSKEY. Mrs. Byron?

Mrs. BYRON. I have no questions.

Ms. PELOSI. I would say, there is a happy coincidence in that Congresswoman Boxer is not only on the Armed Services Committee and is very interested, but is also on the committee that represents the Postmaster General in Congress. He is her constituent.

So I am sure that certainly with the good work of you, Mr. Chairman, and both the subcommittees, our Congresswoman from San Francisco will be a much needed and added spark.

Mr. MCCLOSKEY. Thank you.

We are going to change the schedule a little bit. We are going to hear from Mr. Jeremy Rifkin, Chairman of the Foundation on Economic Trends.

Mr. RIFKIN. Thank you, Mr. Chairman.

STATEMENT OF JEREMY RIFKIN, PRESIDENT, FOUNDATION ON ECONOMIC TRENDS

Mr. RIFKIN. I would like to thank the subcommittees for an opportunity to deal with this very serious issue. I am going to put my written remarks in the record and speak extemporaneously.

The Foundation has been involved for eleven years in monitoring the defense biological warfare program. In 1983 they brought a lawsuit in U.S. District Court related to the testing facility at Dugway, Utah. We were granted an injunction by the U.S. District Court in the District of Columbia.

The Department of Defense has been engaged in developing an EIS dealing with some of the issues being raised here this afternoon. In 1984 the Foundation brought a second lawsuit challenging the biological warfare activities of the Air Force. We also won that lawsuit.

The Foundation and others have expressed grave concern not only about the identity of the agents used in the BDRP, but also about the methods currently being utilized in biowarfare research. The BDRP is involved in large-scale genetic engineering of biological warfare agents.

In a May 1986 report to the Committee on Appropriations of the United States House of Representatives, the Department of Defense pointed out that recombinant DNA and other genetic engineering technologies are finally making biological warfare an effective military option. Genetic engineers are cloning previously unattainable quantities of "traditional" pathogens.

Today's hearing shows there is a good and healthy interest in this issue.

Let me say, there is more of a problem now than fifteen years ago. There is a qualitative and quantitative change in the program of the DOD and the shipment of dangerous and deadly pathogens through the mails and private couriers. In the past ten years the Department of Defense has been working with novel substances and gene splicing technology, creating essentially new forms of existing viruses that we have not seen in the natural setting.

There has been a qualitative change with the gene splicing technology. We now face a whole genre of possibilities that could pose new and unforeseen threats we could not anticipate.

[The statement of Mr. Rifkin follows:]

STATEMENT OF JEREMY RIFKIN

PRESIDENT OF THE FOUNDATION ON ECONOMIC TRENDS

I. INTRODUCTION

I am Jeremy Rifkin, President of the Foundation on Economic Trends (Foundation). The Foundation on Economic Trends (Foundation) is a public interest organization which assesses the economic, environmental and ethical risks involved in emerging technologies. Over the past several years a major focus of the Foundation has been the regulation of developments in biotechnology. A particular concern of the Foundation has been the use of biotechnology and genetic engineering in biological warfare research. In 1985 and again in 1987 the Foundation won law suit victories requiring the DOD to prepare environmental impact statements on its biological warfare research facilities and activities.

The Department of Defense (DOD) is currently involved in significant biological warfare research. This program is called the Biological Defense Research Program (BDRP). This BDRP involves over 120 national and international university commercial and military laboratories.1

The BDRP is devoted to research in "militarily significant" bacteria, viruses and toxins. These pathogens can be used to destroy animals, crops, and people. Biological agents can mutate, reproduce, multiply and spread over a large geographic terrain by wind, animal, and insect transmission. Once released, many biological pathogens are capable of developing a viable niche and maintaining themselves in the environment indefinitely. Traditional biological agents include yersinia pestis (the plague), anthrax, botulism, snake venom, tularemia, rift valley fever, coxiella burnetii (Q fever), eastern equine encephalitis, and small pox. These pathogens are selected for research because they have potential use as warfare agents due to, inter alia, their pathenogenicity, quick infectivity, and ability to rapidly disseminate.2 The BDRP routinely sends these viruses through the mails.

The Foundation and others have expressed grave concern not only about the identity of the agents used in the BDRP, but also about the methods currently being utilized in biowarfare research. The BDRP is involved in large scale genetic engineering of biological warfare agents. In a May 1986 report to the Committee on Appropriations of the United States House of Representatives, the Department of Defense pointed out that recombinant DNA and other genetic engineering technologies are finally making biological warfare an effective military option. Genetic engineers are cloning previously unattainable quantities of "traditional" pathogens. The DOD report states that:

> potent toxins which until now were available only in minute quantities, and only upon isolation from immense amounts of

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> biological materials, can now be prepared in industrial quantities after a relatively short developmental period. This process consists of identifying genes, encoding for the desired molecule and transferring the sequence to a receptive micro-organism which then becomes capable of producing the substance. The recombinant organisms may then be cultured and grown at any desired scale...Large quantities of compounds, previously available only in minute amounts, thus become available at relatively low costs. (3)

Using recombinant DNA technology, it is now possible to develop a nearly infinite variety of "novel" designer biological warfare pathogens never before seen. The DOD report summarizes:

> [new advances in biotechnology]...permit the elaboration of a wide variety of 'novel' warfare materials...The novel agents represent the newly found ability to modify, improve or produce large amounts of natural materials or organisms previously considered to be militarily insignificant due to problems such as availability, stability, infectivity and producibility. (4)

Recombinant DNA "designer" weapons can be created in many ways. The new technologies can be used to program genes into infectious micro-organisms to increase their antibiotic resistance, virulence, and environmental stability. It is also possible to insert lethal genes into harmless microorganisms resulting in biological agents that the body recognizes as friendly and does not resist. It is even possible to insert genes into organisms which affect regulatory functions that control mood and behavior, mental status, body temperature, and other functions. Scientists say they may be able to clone selective toxins to eliminate specific racial or ethnic groups whose genotypical make-up predisposes them to certain disease patterns. Genetic engineering can also be used to destroy specific strains of agricultural plants or domestic animals if the intent is to cripple the economy of a country. In recent months advances have been made in the creation of genetically engineered microbes which are designed to self destruct after a given period of time. The implications of this, and other advances in genetic engineering, are extraordinary and frightening.

Douglas J. Feith, Former Deputy Secretary of Defense, noted the near impossibility of defending against this newfound ability to genetically engineer biowarfare agents:

> It is now possible to synthesize BW agents tailored to military specifications. The technology that makes possible so-called "designer drugs" also makes possible designer BW....It is [becoming] a simple matter to produce new agents

> but a problem to develop antidotes. New agents can be produced in hours; antidotes may take years. To gauge the magnitude of the antidote problem, consider the many years and millions of dollars that have been invested as yet without success, in developing a means of countering a single biological agent outside the BW field -- the AIDS virus. Such an investment far surpasses the resources available for BW defense work. (5)

Due primarily to genetic engineering the BDRP has expanded 500% over the last 6 years. In 1981, the Pentagon budget for "defensive" biological warfare research was only $15.1 million. In fiscal 1982 it rose to $21.6 million. In fiscal 1983 it jumped again to $38.8 million. In 1984 it rose still higher to $39.1 million. In 1985 the DOD budget grew to $50 million and in 1986 to $90 million. (6) The various branches of the Armed Services now work with virtually every major pathogen in the world from hemorrhagic fevers to exotic virus disease like Chikungunya and Mayaro to newly discovered viruses like AIDS. The Department of Defense claims that most of the work is unclassified and intended to provide the United States military with defensive protection in the form of vaccines and antidotes. Despite the Department of Defense assurances that its biological warfare program is defensive in nature and not in violation of the Biological Weapons Convention, many observers are alarmed over the increased commitment of funds for genetic engineering research.

II. ENVIRONMENTAL IMPACT

The exponential growth of the Biological Defense Program (BDRP) over the last seven years has the potential for significant adverse effects on the environment and public health. According to the DOD, biological warfare research is ongoing in more than 19 government labs, 50 non-governmental research labs and institutions, and over 85 colleges and universities. As noted this research involves numerous bacteria strains such as Salmonella marcescenes, and Yersina pestis, numerous viruses including Rift Valley Fever, Yellow Fever, poliovirus, Ebola and Marburg viruses and human retroviruses; and more than seventy toxins, including T2 mycotoxin, Scorpion toxin, and Mojave rattlesnake toxin. The BDP has also conducted over 75 recombinant DNA experiments.7

Senator Orrin Hatch (R-UT) has maintained that biological warfare experiments in populated areas constitute "reckless endangerment" and has advocated "a remote island for any future biotoxin work."8 The environmental impacts of this research brings up the following concerns: 1) effects on the general public from potential exposure to biological warfare agents during normal operations or due to advertant or inadvertent

release of the hazardous organisms (i.e. human error, equipment failure, terrorism, or natural disasters); 2) effects on DOD personnel from potential exposure to biological warfare agents being researched; 3) impacts on air, and water quality and biota from BDP operations or accidents; 4) laboratory security; 5) risks involved in decontaminating facilities; 6) treatment and disposal of BDP research wastes; 7) economic and social impacts to areas adjoining BDP sites, and 8) the focus of today's hearing, transportation and shipping of BDP pathogens.

Despite our successful law suits and growing public concern there has been no independent investigation into the number of shipments being undertaken under the BDRP, or the amounts of pathogens contained in each shipment. The DOD admits that one of its major army installations makes an average of one shipment a week of BDRP biological warfare agents.9 The DOD has not provided figures for the other laboratories. However, at a minimum, the BDRP is involved in several hundred shipments per year. Recent testimony by DOD representatives before Congress revealed that the military is planning to substantially increase both the number and amounts of shipments as well as the toxicity of the agents being shipped as it continues the rapid expansion of its biological warfare program. As described above, these BDRP pathogens include the most dangerous biologic materials known to man, many altered or created through genetic engineering.

Reported cases of missing viruses including the loss of a sample of Crimea Congo hemorrhagic fever en route from the Center for Disease Control to the BDRP lab at Fort Detrick, Md. add urgency to the need for a moratorium on the shipment of BDRP etiologic agents.10 According to the National Institutes of Allergy and Infectious Diseases the Congo fever virus is so "highly infectious" that "most labs won't work on it."11 With this virus, and many others being worked on in the BDRP labs even small amounts of the pathogen if dropped from a plane or truck or dumped into the water supply, could have devastating effects.

Remarkably, given the expansion of the BDRP and the exponential growth in the use of genetic engineering, the DOD is relying on safety standards in its packaging and shipment of BDRP pathogens which were tested and established almost twenty years ago.12 Those studies are out of date and require significant retesting and revision.

The hazards of shipping BDRP pathogens has led the Foundation to officially request that the U.S. Postal Service and Department of Transportation immediately suspend all shipments of DOD etiologic agents under the BDRP. We believe that it is irresponsible to allow any further transport of biological warfare agents. A moratorium on the shipment of BDRP agents

should be implemented until the DOD provides complete and detailed information on all shipments which have been made pursuant to the BDRP over the last 6 years. And until the DOD conducts and publishes updated tests of the packaging of BDRP agents to establish new safety standards and protocols for the shipment of such agents. These new protocols should be subject to full public comment and review prior to promulgation.

Footnotes

1. See list of laboratories involved in BDRP research in Draft Programmatic Environmental Impact Statement, Biological Research Defense Program, May 1988, Appendix 3.

2. See partial list of BDRP pathogens Answer to Plaintiff's Interrogatory No. 4, Foundation on Economic Trends et al v. Weinberger et al., Civil Action No. 86-2436.

3. Department of Defense Biological Defense Program, Report to the Committee on Appropriations House Representatives, May 1986, p. 4.

4. Ibid., p. 4.

5. Testimony of Douglas J. Feith Before the Subcommittee on Oversight and Evaluation of the House Permanent Select Committee on Intelligence, August 8, 1986.

6. Tucker, pp. 60-69. See also: Department of Defense Annual Report on Chemical Warfare, Biological Defense Research Program Obligations Oct. 1, 1984 through Sept. 30, 1985, RCS: DDUSDRE (A) 1065.

7. See footnotes 1,2.

8. "Hatch Proposes Island Location for Germ Warfare Testing," Press Release, Office of Sen. Hatch, March 25, 1988.

9.See Programmatic Environmental Impact Statement, Biological Research Program, A2-6.

10. Associated Press Wire Report, The News, Frederick, M.D., Saturday May 30, 1987, A-5.

11. Ibid.

12. Draft Programmatic Environmental Impact Statement, at A2-7.

Mr. MCCLOSKEY. Would you comment on the possibility or likelihood of faster easy breeding and multiplication of these viruses?

As you know, DOD says it will dry up in the container, near zero impact.

Mr. MCCURDY. Would you yield?

Mr. MCCLOSKEY. Yes.

Mr. MCCURDY. I would very much like to see the evidence the gentleman has to support that statement. If he does have a record or actual evidence of any kind, I would like to see it, because that is a very serious statement. I, for one, think the subcommittee needs to have some documentation or supporting information to back that statement.

Mr. RIFKIN. Yes. In fact, that information is on the public record. During the process of discovery in our two lawsuits, we were provided an extensive list of experimentation going on by the DOD. Included in that list are 54 different recombinant DNA experiments, many gene splicing/cloning experiments, including anthrax and other agents.

I would be very happy to provide that information to the committee, as we have to the Senate committee. It is public record and it is in the discovery part of our lawsuit.

[The information follows:]

Mr. RIFKIN. Let me try to respond to the Chairman's inquiry and quote the Department of Defense.

Mr. MCCLOSKEY. They say you are from Mars. I assume that is not your address.

Mr. RIFKIN. I caught that comment in the press. In fact, if any of these accidents do occur, it might be better to be on Mars.

DOD issued a report talking about the possibility of developing new gene-spliced organisms and deadly toxins. The report says potent toxins which until now were available only in minute quantities, and only upon isolation from immense amounts of biological materials, can now be prepared in industrial quantities after a relatively short developmental period. This process consists of identifying genes, encoding for the desired molecule and transferring the sequence to a receptive micro-organism which then becomes capable of producing the substance. It essentially acts as a factory to produce the dangerous material.

The recombinant organisms may then be cultured and grown at any desired scale. Large quantities of compounds, previously available only in minute amounts, thus become available at relatively low costs.

Using recombinant DNA technology, it is now possible to develop a nearly infinite variety of novel designer biological warfare pathogens never before seen.

The DOD report summarizes that new advances in biotechnology permit the elaboration of a wide variety of novel warfare materials. The novel agents represent the newly found ability to modify, improve or produce large amounts of natural materials or organisms previously considered to be militarily insignificant due to problems such as availability, stability, infectivity and producibility.

It is now possible to synthesize BW agents. The technology that makes possible designer drugs makes possible designer biological

warfare. It is becoming a simple matter to produce new agents. But antidotes may take years.

To gauge the antidote problem, consider the millions of dollars and years that have been put into developing a biological agent for the AIDS virus. Such an investment far surpasses the resources available for BW defense work.

Mr. MCCLOSKEY. May I ask a specific question before we take a 15 minute recess to allow Members to vote.

I am fairly new to this area. In a DOD briefing and from what we will hear from the DOD representatives today, they will show you the three containers, the sealing of the canisters. I understand there is a film in which a cargo plane crashes against a mountain and the canister pops out unbroken. They say all viruses and pathogens and what-not are just so unlikely to live outside the lab's natural conditions, normal temperature, sunlight, et cetera. The absorbing substances in the container itself mean that—and they won't promise it absolutely—nothing is going to live outside that canister.

Can you talk from some knowledge as to whether these organisms can breathe in the air, the water and the human environment, et cetera?

Mr. RIFKIN. I will comment briefly, and after your recess we can go into more detail.

The fact is that these agents, many of them, have to be useful in the outside environment. If the DOD is saying these cannot survive, then we are wasting taxpayers' money.

Mr. MCCURDY. That is a point I want to follow up with Mr. Rifkin.

Is it not the case that these so-called labs, the DOD labs, are actually using these toxins in order to determine their lethality as potential agents used against U.S. citizens and forces, and that they are indeed developing defensive measures. We are not developing biological warfare capabilities ourselves, but the United States Government is trying to protect itself and, if anything, becomes defensive on this issue, as opposed to developing an offensive biological warfare capability. An offensive biological warfare capability I am not sure you are saying we are responsible for, but it is getting close.

Can you give me a clarification?

Mr. RIFKIN. I think it is important to clarify.

We are signatories to the Biological Weapons Convention. That says we cannot do offensive work but can do defensive research work.

The problem is—many scientists have testified before congressional hearings and in our lawsuits on this—the micro-organism doesn't know whether it is offensive or defensive when you are shipping it through the mail. You must first have the offensive agent to develop a defensive agent.

The purpose of these hearings, as I gather, is to look at the environmental questions and health and safety questions in transporting these materials, rather than the more complex question of biological warfare and the questions of disarmament and our relations with the Soviet Union and other countries.

In terms of the danger present, the important point to emphasize over and over again is that these deadly organisms have to be used in order to develop defensive research. It is the safety of the public and the research lab workers we have to take into account here.

Mr. McCURDY. I agree with the statement the gentleman just made, but I think it should be absolutely clear that this subcommittee knows, first of all, we are not developing offensive capability and, secondly, that these joint subcommittees convened these hearings in order to investigate the standards for safety and the transportation in the mails or otherwise. That is what we are here for.

Many of us were surprised and shocked to see some of the statements. But I think it is important that those headlines emanating out of this hearing—and some people are better at making headlines than others—do not read that we are shipping deadly toxins. To start a panic or fear based on this, I think, is unwise.

Mr. RIFKIN. I agree 100 percent. I would hope my testimony has been contained to the factual evidence. I am surprised the Congressman brought this up.

There are other congressional committees that deal with war and peace and disarmament.

Mr. McCLOSKEY. We are concerned, I think that is implicit and explicit in the record, for transportation, safety and environmental hazards.

This is not a hearing on the efficacy of developing biological capacities or whatever.

Mrs. Byron.

Mrs. BYRON. Let me interject a couple of comments here.

I think we are talking about my District in many cases. I think we have seen a situation and, had we had the witnesses in the proper chronological order—I think, Mr. Rifkin, if you had testified after Mr. Miss, the postal employee in Frederick, Maryland, I think your testimony would have come under a different category.

The testimony states the problem which occurred in November 1987 in his post office when he was on duty and what has transpired in the meantime, and how his comments and concerns, working with the people who were the shippers, have probably relieved and improved the situation.

It is my understanding that this is an oversight hearing on shipping, on the utilization of the mails, on containers and the quality and capability of those containers, and the designation within the public sector of the post office and transportation. I think some of the testimony that will be developed here this afternoon will address those issues in a different light than the issues you are trying to develop today.

Mr. McCLOSKEY. I don't think there is anything improper in Mr. Rifkin's testimony. I don't think he has contradicted the purpose of this meeting.

Be that as it may, we will have to recess for 15 minutes to vote.

[Recess.]

Mr. McCLOSKEY. We will resume the hearing.

Mr. Rifkin, do you want to finish?

Mr. RIFKIN. Mr. Chairman, as I was saying, there has been a qualitative and quantitative change in the biological warfare program in terms of shipment of various agents through the mail. I

mentioned the qualitative change. The quantitative change is as important.

The fact is the present Administration increased its biological warfare work, research work, by 500 percent in five years. The DOD is shipping pathogens to 129 university, corporate and military laboratories across the country for research purposes. I have a list here of some of the more deadly viruses and bacteria that are being shipped through the Postal Service and private carriers.

They include the plague, Riff Valley fever, Crimea Congo hemorrhagic fever, Venezuelan encephalitis, Japanese encephalitis, polio virus, Mojave rattlesnake toxin, scorpion toxic and cobra toxin. These are very, very dangerous pathogens to be putting through the mails and through private carriers as we are presently.

I believe there are two levels of concern that we need to address when transporting these pathogens through the mail. The first is the question of accident. The second is the question of security breach and possible sabotage or terrorism. Obviously, the first is more likely than the second. Both are unlikely, but they are something we should take into consideration.

Earlier, Senator Levin, and I believe the chairman, when you opened up the session, mentioned the Crimea Congo Hemorrhagic virus. When they found out that virus didn't show up at the designated spot, Fort Detrick, it was suggested they check the dead letter file at the Post Office. That is rather a shattering realization if that is the state of the security in terms of this.

I might point out something this committee is not aware of. In 1984, two Canadians using the telephone and mail order, were able to secure tetanus and pure botulism culture. They did it using bogus letterheads. The U.S. Attorney Joseph Guerrera III said, in prosecuting these gentlemen, "You can poison the whole water system with these agents. They got to be strictly controlled. If they got into the hands of terrorism, we would all be in trouble."

These two men were convicted by a U.S. Federal Court. They simply took it upon themselves to get a hold of the American Tissue Culture Lab and get these dangerous pathogens. They had them sent in this case through a private carrier, Federal Express.

One of the interesting questions always raised is how dangerous are these organisms? Obviously, they are small amounts. The problem is, you cannot equate the amount with the danger. When you are dealing with viruses, you have contagion and ineffectivity.

Dr. Richard Goldstein, in talking about the shipment and handling of these microorganisms, said the following: "All one needs is the smallest vial I could hold between my fingers for some types of organisms. In that vial, I could put more organisms than there are people on the face of the earth. I could take that vial and either I could drop it from a plane, dump into a water supply or some other place where people could be contaminated by it.

"Then I would need only one of those particles to infect someone. Once that person was infected by that virus, they would produce that virus and spread that virus in the same way that normal viruses are spread."

I think that gives us a sense of the problems. When you develop novel changes in viruses or new modifications in viruses to which

there are no vaccines and no medical way to address them, you are dealing with a potentially very catastrophic situation.

The present protocols in place by the Department of Defense were issued in 1970, 18 years ago. They were first put together in 1969. Those protocols are outdated. They do not take into consideration the qualitative and quantitative changes that I have been discussing here in this testimony.

It is also important to address the question of procedures in case there is an accident or terrorism. The fact is, most postal workers and private carriers across the country have received no training at all in dealing with accidents and security breaches.

It is also important to notice that there are no protocols or regulations in place by the Department of Defense with local authorities. Local police departments, fire fighters, local health authorities have no protocols that have been given to them on how to deal with an accident or sabotage. There are no protocols in place to deal with mass evacuation of a local population in case of an accident.

There are protocols to deal with emergency medical treatment. There are no protocols to deal with quarantine. In fact, the only thing the protocols do say is call—I believe it is an 800 number. Call the Centers for Disease Control in an emergency situation. That is not adequate for a crisis in a local community.

These post offices, private carriers are often in the middle of large urban areas. Not to have any protocols for fire, emergency medical, quarantine and emergency evacuation is begging for an accident that we will all regret.

A few other items. When the whole question of dealing with deadly pathogens was raised in January in the State of Utah, it is interesting to recount what the State officials had to say there.

Dugway will be receiving and sending deadly and dangerous pathogens all over the country. It is going to be one of the key centers, as is Fort Detrick. Now, the State of Utah was so concerned about the building of a biological warfare laboratory at Dugway, Utah, that the Governor of the State issued a statement in January saying at the present time, he believes the Department of Defense's facility is too potentially dangerous and the State would take whatever means necessary, within their power, to ensure at this time the facility is not built.

Further, one of your colleagues here in the Congress, Senator Orrin Hatch, Republican of Utah, issued a press release. He said that it was reckless endangerment of the Pentagon to even suggest building this laboratory to house these dangerous viruses in the desert of Utah. He said it was unconscionable to subject Utahans to the potential of an accident if any of these viruses were to escape this kind of high technology laboratory.

Mr. McCLOSKEY. I have not seen his statement, but I am aware of your formal statement. Did he suggest the work should be done on an island?

Mr. RIFKIN. He suggested an island a mile by a mile and a half. This island is being suggested to house almost everything now. That is what the Senator from Utah suggested.

Now, what I want to do is compare the perceived danger in that lab with the danger in shipping. The laboratory that they are pro-

posing is highly contained. It is contained with glass and steel barriers. There are glove boxes, hoods, special gowns to make sure those viruses do not create a situation of infection or escape.

Those pathogens they are protecting with those potential security provisions, which even the Senator suggested are not adequate, those pathogens are being shipped to and from that laboratory from all over the country.

Here is one of the quotes from the Department of Defense regulations on how they deal with those pathogens when they put them through the mails or private carriers: "Materials should be placed in a securely closed water-tight container and tested." Then they suggest there be some absorbent material in that container.

I believe Senator Hatch is right and the Governor of Utah. If it is too dangerous to house these viruses with all the containment facilities being suggested in Utah, certainly it behooves us to look at the potential problems in shipping these materials with the existing protocols in place.

Finally, we—the Foundation on Economic Trends—two weeks ago petitioned the Secretary of the Department of Transportation and the Postmaster General of the United States. Our attorneys have requested that the Secretary of Transportation place an immediate moratorium on the shipment of DOD pathogens that are dangerous or deadly, to provide a short period of time so that the Department of Transportation can request an audit of the DOD of the shipments over the past five years and potential problems, accidents, and to allow the DOD a small period of time, the Department of Transportation, to look at the existing protocols to find out if there are any inadequacies, and then to make recommendations for new protocols that would ensure public safety and the safety of workers that are dealing with these pathogens.

It seems to me that is a responsible short-term measure. If that isn't forthcoming by the Department of Transportation, I would hope the Congress of the United States would take it upon itself to develop the precautionary updated legislation so we don't have a potential tragedy on our hands in the years ahead.

Thank you, Mr. Chairman.

Mr. McCLOSKEY. Thank you, Mr. Rifkin, for a very interesting and comprehensive testimony. I, for one, very much appreciate it. I think what you say are points to transportation and environmental hazards. I certainly appreciate that.

I have a feeling, with the complexity and general interest of this issue, that we are going to have at least several more hearings.

At this time, I would like to apologize to various witnesses today, since the order is changing. But various concerns are coming up as to schedules and conveniences of witnesses. I am here for the remainder to hear everyone.

We would like to hear now from Mr. Gerald Miss, an employee of Frederick, Maryland, Post Office. Thank you for being here today, Mr. Miss. I know something about your situation and appreciate your interest and commitment in appearing before this joint hearing.

You have had a very valuable experience and insight. Please proceed.

STATEMENT OF GERALD MISS, EMPLOYEE, U.S. POSTAL SERVICE, FREDERICK, MD

Mr. Miss. Thank you.

My name is Gerald Miss. I am a mail handler at the Frederick, Maryland Post Office. I have been working for the U.S. Postal Service since November of 1986.

My reason for appearing here today is to report on an accident that happened in November of last year and to relate other incidents involving biohazardous materials and biological products that have occurred in our office.

On November 10, 1987, I was working on the incoming First-Class Mail belt. This was on Tour One, midnight to 8:30 a.m. As a mail handler, part of my duties include dumping sacks, pouches and hampers of mail onto the belt where it is culled and separated as to type—parcels, flats, letters, et cetera—and where it is thrown off into containers for further distribution.

At approximately 12:15 a.m., I picked up an express parcel that had come in from the dock. It was a styrofoam parcel containing flu vaccine, packed in dry ice, which was to be delivered to our local health board for vaccinations later in the week.

When I picked up the parcel it was dripping. It dripped on my hands and the front of my apron. I immediately reported this to my supervisor. Since dry ice dissipates and doesn't melt, it was obvious the contents had been damaged.

With the help of my supervisor, the parcel was sealed in a plastic bag to contain the spill. I then washed up as a precaution against possible contamination.

Though this spill did not result in an illness—most likely because it was a killed vaccine—it points, in my opinion, to a potential threat due to the nature of some of the mail that passes through our office.

The Frederick office, though not unique, is, I believe, at greater risk than most offices in the Postal System because of the agencies it serves. USAMRIID and the National Cancer Institute are both located at Fort Detrick.

It is my understanding that there are plans to build an AIDS research clinic at Fort Detrick as well. We serve two hospitals and there are a variety of laboratories in our area. Most of these agencies work with biological products, some of which are etiologic in nature. A number of these specimens go through our office in the mail. These specimens frequently are not packaged and labeled in accordance with postal regulations.

Canisters labeled "RETROVIRUS," a class of viruses to which the AIDS virus belongs, come into our office in sacks with other mail. When the sacks are dumped, the lids from the canisters come off because they have not been reinforced with tape.

On occasion, the test tubes containing blood specimens have spilled from the canisters onto the belt. The tubes were wrapped with bond paper rather than absorbent material. Fortunately, not one tube has ever broken in our office.

Urine specimens have broken on the belt, though, because they were shipped in envelopes rather than non-permeable secondary containers with absorbent material surrounding them, as required

by regulation. I personally know of two specific instances when urine samples have broken on the belt.

I have seen styrofoam parcels going to the "Rickettsia Research Facility" at Fort Detrick. If the parcel contained rickettsiam, there was no indication as to what disease it contained. If it was a live rickettsia, it had no biohazard label on the container.

At the time of my accident, our office was not equipped to handle a biohazardous spill. Since that time, and largely due to the efforts of our acting Superintendent of Processing Operations, Mr. Tim Haney, and the Supervisor of Administration, Mr. Howard Huegel, we have initiated a hazardous materials program.

I was given the task of researching the problem, gathering together all postal regulations, disposal procedures, items needed for handling a spill, and drawing up a list of recommendations I felt would help to avert or minimize future problems.

Some of these recommendations include training personnel to handle such spills and educating personnel as to postal regulations so when parcels do not meet postal standards, they may be reported.

I have asked that all biological products be segregated from the mail into separate containers and sacks; labeling them appropriately in order to alert other offices as to the nature of their contents so they may be handled properly.

The necessary items for handling a spill have been acquired and are kept within 20 feet of the belts, along with the telephone numbers of the agencies to be notified in the event of a spill.

Letters have been spent to a number of the mailers that handle these agents, along with copies of postal regulations concerning packaging. I am happy to say that the canisters I mentioned earlier began coming through our office sealed with tape to prevent their spilling on the belt.

Our office is also drafting "follow-up" letters and notices to be sent to those mailers who continue to violate packaging regulations.

I have also designed a container for biological products that meets all postal regulations. I plan to submit the plans for this container to headquarters for approval.

I have been asked to train other personnel and give safety talks to our employees, as requested in my recommendations.

In conclusion, I would like to say that since postal employees are not trained scientists, I feel that they should not be expected to handle, much less make decisions on the disposal of, hazardous biological materials, or be submitted to the possible threat of contamination.

Mr. McCLOSKEY. Mr. McCurdy, good to see you back. Do you have any questions or comments?

Mr. McCURDY. Thank you.

Certainly I am sympathetic to the incident which occurred. I appreciate your efforts in trying to change your regulation.

Can you just tell us, as a person who has handled mail, the percentage of the mail from different agencies that would have some type of substance in it that would fit in the category that concerns you?

Are you saying it is mainly DOD? You said cancer research?

Mr. MISS. National Cancer Institute.

Mr. MCCURDY. Flu viruses. The one that spilled on you was flu virus?

Mr. MISS. It was a flu vaccine.

Mr. MCCURDY. This is an industry-wide situation—not just Federal agencies? Private companies ship biological materials through the mail also?

Mr. MISS. Exactly.

Mr. MCCURDY. This is clearly is postal responsibility, since they enact regulations. They are going to have to address the situation. That is where you are coming from. You are asking them to improve their regulations in handling and restrict the mailing of certain types of substances? Is that correct?

Mr. MISS. That is true. We don't only get parcels in the mail from DID, but other agencies. Retrovirus canisters come from the Maryland Board of Health.

Mr. MCCURDY. Can you give us a description, because I have not seen any of these. When you say a vial, are you talking about things as small as the case used to send contact lenses through the mail or are we talking big tanks?

Mr. MISS. The canisters I had mentioned containing retrovirus are roughly three inches in diameter, maybe six to eight inches high, cardboard canister with a tin lid that screws on. Inside are a number of test tubes, rubber stopper, containing blood specimens. There have been occasions when these have spilled onto the belt, because they have not been packaged properly.

Mr. MCCURDY. It does not seem like a smart way to package things, in test tubes? With zip-lock bags and all these new procedures, you would think there would be a smarter way to do that.

Can you tell me just from a post office operating standpoint, if it is a registered letter or registered mail, does it still go through the same post office, or is it handled just in a more expeditious manner, or is it hand-carried in some way? Tell us the routing process here.

Mr. MISS. Registers are given special attention. But they come into our office. They are usually placed in the tops of containers that are taken from the trucks so they can be seen immediately, and they are grabbed and taken into our office, where they are then taken to the register cage. The register clerk will then open those. They come in in pouches unless it is very large. But it is in a canvass pouch.

The letters are strapped with a large brass lock on it. The register clerk opens them, checks the numbers and the paperwork against the numbers on the parcel. All of that is recorded. The numbers on the lock are recorded. It is closed up again and sent to wherever it is going.

Mr. MCCURDY. In overnight delivery, would that be handled even separately from the registered?

Mr. MISS. Yes, it is, express mail is. They come in special bags. They are orange and blue bags. As soon as they are seen on the containers, they are taken to the truck. They are grabbed. The person working the express mail will open those, find where they are going and then send them to respective offices.

Mr. McCURDY. I worked my way through college loading trucks on a dock. I hoped mail wasn't loaded the way I loaded trucks. Are these canisters likely to have large parcels on top of them? Are they likely to have things dropped on them, kind of like my luggage going through the airlines?

Mr. MISS. It does happen. Some of the mail would be put in the hampers. In processing the mail, the parcels are thrown into the hampers. The smaller canister or smaller parcel might go in first and a large one in on top of it. It is very easily done.

The hampers are dumped onto belts, where they are sorted. If large, if a small parcel is on top, the heavier parcel will come down on top of it.

Mr. McCURDY. What is the largest parcel you have seen come through the mail, just kind of an idea of how large things are?

Mr. MISS. You mean in reference to this kind of material, or in general?

Mr. McCURDY. In general. What is the biggest thing that is shipped in the mail? What is the biggest thing you can lose, is what I am asking you.

Mr. MISS. There was one the other day that was possibly 24 inches high, maybe a little larger, by 30 inches.

Mr. McCURDY. Twenty-five, 30 pounds, something like that?

Mr. MISS. Probably more, because two of us lifted it.

Mr. McCURDY. Is there a weight restriction?

Mr. MISS. Supposedly nothing more than 70 pounds.

Mr. McCURDY. I was always curious what happened to those things that I never see again. What happens with stuff that is lost? I mean, if a label is ripped off or ink smears or something, is there a standard handling procedure? Assuming anything was ever lost, where would it go? What would you do with it?

Mr. MISS. That is not part of my craft.

Mr. McCURDY. I know you don't lose things intentionally. If anything came in that was unidentifiable, there was no return address on it, and there was no addressee either, what would you do with it?

Mr. MISS. Depending on what type of piece of mail it is, magazines or letter mail, sometimes letter mail is shredded in the canceling machine.

Mr. McCURDY. At individual post offices?

Mr. MISS. We have a shredder called a Mark 2.

Mr. McCURDY. Do you have some supervisor or someone who makes that determination?

Mr. MISS. The supervisor would. Mail that is damaged, letter mail, is usually put in a tray if it can be patched.

Mr. McCURDY. Is it opened first to see whether you can identify if it is a letter to grandmother and the address, but you open it first to see what is in it before you dispose of it?

Mr. MISS. The supervisor would take care of that. If it is a magazine, it is thrown away.

Mr. McCURDY. Class 2.

Mr. MISS. Third-class mail is thrown away.

Mr. McCURDY. If it were a box, would the box be opened?

Mr. MISS. I would think so. I have never actually seen it done.

Mr. McCURDY. There is not a central dump or something, that you are aware of?

Mr. MISS. Other people here I know can tell you more about that.

Mr. McCURDY. There was one report of something that was lost, and they say for a year they haven't found it. I am curious about what happened to something like that. Is there a huge warehouse? Is there a warehouse that they put these things in next to the Ark of the Covenant? It is sitting in the warehouse down here on E Street or something?

Mr. MISS. I do know things are sent to the dead letter office, but I don't know what the procedure is for doing that.

Mr. McCLOSKEY. We will have a Postal Service——

Mr. McCURDY. I was trying to find out from the operator's standpoint, what happens to lost articles, Mr. Chairman. I appreciate that. Of course, I am not on the Post Office Committee, but I certainly believe that the employees who work in the Post Office are doing a valuable job for our country. We don't appreciate the service until something happens. It is kind of like the phone—we don't appreciate them until they don't work, which they haven't been here lately. AT&T has dropped this one.

Anyway, we do appreciate what you do. I was just trying to find out from your standpoint, your perception of the regulations and the actual operations, thank you for your testimony today.

Mr. MISS. Thank you.

Mr. McCLOSKEY. Mr. Miss, I have two or three brief questions. I would like to go on longer, but people have been waiting.

Could you relate subjectively what you felt when this stuff spilled in your hands?

Mr. MISS. Subjectively, it scared me.

Mr. McCLOSKEY. Did it concern you at the time with the mystery of it?

Mr. MISS. Not knowing what this could have been, it did scare me.

Mr. McCLOSKEY. As it turned out, it was nothing lethal. But the point is, it could have been a package with a lethal substance. It was a matter of some luck that was not the case.

I really do appreciate your efforts to assert leadership given your problem in the workplace. You have become very scientifically and environmentally oriented at Fort Detrick, giving training sessions and so forth. You partially alluded to the fact that up until then—and I know the Post Office has a somewhat dramatic decision that may be related to us in a little bit—there is no overall Departmental policy on this to speak of as yet.

Would you say that is true? I am just concerned where you are getting scientific back-up for your efforts.

Mr. MISS. I am not sure what you are referring to.

Mr. McCLOSKEY. Emergency and sanitation procedures and so forth, as to what to do in the event of a spill.

Mr. MISS. There are some guidelines. There are guidelines given in the Publication 52, for acceptance in handling hazardous material, disposal procedures.

At the time, I didn't know what they were. I looked at those since then. There have been some guidelines sent to me from our region in Baltimore.

Mr. McCLOSKEY. As you say, you were given the task of researching the problem. With all due credit to you, I have a tendency to doubt, however, that you have a Master's in engineering from MIT. We have lawyers in our Postal System in Bloomington. You have taken a lead in researching the problem. I find that interesting.

Mr. MISS. I was given the task of researching the problem. I was asked by management to look into what we should do, what we can do, that sort of thing.

Mr. McCLOSKEY. As you say, at the time your area was not equipped to handle a biohazardous spill?

Mr. MISS. Right.

Mr. McCLOSKEY. I thank you very much for being here, Mr. Miss. Is there anything else you care to add?

Mr. MISS. No, I think not. Thank you very much.

Mr. McCLOSKEY. Thank you.

Mr. Biller, I understand you have a severe schedule problem this afternoon. Perhaps you would want to come forward. Good afternoon, Mr. Biller. Thank you for being here. Please proceed.

STATEMENT OF MOE BILLER, PRESIDENT, AMERICAN POSTAL WORKERS UNION, AFL–CIO

Mr. BILLER. Good afternoon. Thank you for the opportunity to be present here today. On my right is Michael Reid, Legislative Staff. On my left is Mr. Anton Hajjar, General Counsel's Office, American Postal Workers Union.

I am Moe Biller, President of the American Postal Workers Union, AFL–CIO. The American Postal Workers Union is the largest postal union in the country, representing over 365,000 active and retired postal workers nationwide. I am pleased to appear before the committees this afternoon to comment on the U.S. Army's proposal to ship biological toxins in the mail.

If one were to summarize the recent developments in the proposed shipment of biological warfare agents via the U.S. Postal Service, one could not find a word more appropriate than "bizarre." Bizarre in the sense that one cannot believe that the United States Army would approve and plan shipment of infectious and toxic agents by ordinary registered mail. Bizarre that an environmental impact statement would not be forthcoming until a lawsuit was initiated—and bizarre that upon discovery of this devious scheme, the U.S. Postal Service did not reject the planned shipments forthwith.

As one would expect, the U.S. Army has not fully disclosed the chemical composition of the agents planned for shipment. Some information is contained in a draft environmental impact statement which resulted from a lawsuit brought by an environmental group. The California Attorney General's analysis of the draft EIS states the following:

> Testing will include bacteria and viruses capable of causing debilitating or fatal diseases or reactions. The EIS explains that some of the agents are infectious at extremely low exposures. These include Q virus, botulism and anthrax. VEE, Venezuelan Equine Encephalitis, is not indigenous to North America and therefore could have serious ecological repercussions if released because the local flora and fauna have no known natural resistance.

It is common knowledge throughout the scientific community that botulism and anthrax viruses are extremely infectious and toxic. These and the other agents are sufficiently dangerous to use as weapons of war. The EIS fails to adequately inform just what agents are intended to be shipped through the mails.

The press knows a good story when they see it, so a number of news stories have appeared in the media. Consequently, the public is now concerned. The American Postal Workers Union is also deeply concerned because it is our members who will come into direct contact with the containers as they are processed through the mail stream.

Mr. Chairman, we postal workers are extremely proud that we are the ultimate universal common carrier for all mailable shipments. We carry everything from baby chicks to live scorpions to medical samples, including AIDS and herpes samples.

But common sense dictates that certain items should be mailed only with extremely prudent precautions, and some are so inherently dangerous that they should not be mailed at all. Registered mail, the proposed means of delivery, while segregated from other classes of mail, offers no special handling procedures that would provide an absolute guarantee against rupture or fire.

Section 1716 of the U.S. Criminal Code identifies a long list of non-mailable items. In general terms, it states that any "materials which may kill or injure another, or injure the mails or other property, whether or not sealed as first-class matter, are non-mailable matter, and shall not be conveyed in the mails."

The same statute authorizes the USPS to allow such matter to be mailed under regulations providing for safe handling, labeling, packaging, and the like. However, the law states that the USPS may not permit the mailing of matter which are "outwardly or of their own force dangerous or injurious to life, health or property." We think biological warfare agents fit this description.

The USPS's mailability rules are found in the Domestic Mail Manual, DMM, and Publication 52, Acceptance of Hazardous, Restricted or Perishable Matter, as well as numerous other regulations. We understand that the USPS is concerned that the Army's proposals may be allowed under DMM Section 124.38, covering "Disease Germs and Biological Products."

They should not be so concerned; it is clear from the context of this section and the parts of the U.S. Code from which it is derived, that the domestic mail manual refers to medical specimens or biological agents for medical or scientific research.

The Army's shipments are weapons, like bombs and guns, which are simply not mailable. They should be excluded as such. Or else they may be excluded as Class A poisons, which are addressed in DMM Section 124.361(b) as follows:

"Class A poisons are extremely dangerous gases or liquids of such a nature that a very small amount (oral lethal dose (LD) less than 5 milligrams to kilogram of body weight of test animals) is fatal to half of the test animals within 14 days, for example, phosgene. Class A poisons are not mailable under any conditions."

We have no doubt that the USPS's attorneys can find a way with little ingenuity to keep these extremely dangerous substances out of the mails.

These plans, however, raise more fundamental issues about the highly dangerous matter which enter the mail stream regularly; for example, AIDS samples, hepatitis B samples and toxic chemicals.

The USPS's mailability rules are bewildering on their complexity, and are scattered through a number of manuals and handbooks, including the regulations of other agencies, such as the Department of Transportation and Public Health Service. A few examples of these sources are listed in an appendix to this testimony.

Let us assume for the moment that the proposed Defense Department toxic agents are classified as disease germs under the DMM. These so-called "etiologic agents' are mailable only "when it is determined that such items are properly prepared for mailing to conform to Federal requirements applicable to interstate transportation of such matter." In addition, they "must have required marking affixed."

The Public Health Service rules governing "Interstate Shipment of Etiologic Agents" is found in 42 CFR Part 72. The DOT's regulations covering "Poisonous Materials, Etiologic Agents, and Radioactive Materials" are found in Subpart H of Title 49, Part 173 of the Code of Federal Regulations. Incidentally, the DMM is not published in the Code of Federal Regulations.

So what does a postal retail clerk do if one suspects the contents of such a package? There is neither the time nor opportunity to review all of the appropriate documents if they were made available. Customers are waiting, and a snap decision must be made.

Appeal rights are provided to mailers to challenge refusals to accept items; it is not clear whether these appeal rights are available to postal workers and the public when the USPS accepts such matter. Unfortunately, the USPS errs on the side of acceptance, not caution.

Let me quote a memorandum from an August 1987 directive by Assistant Postmaster General Stephen E. Miller to all Regional Postmasters General dealing with acceptance of "Disease Germs and Biological Products:"

"It has been our position that refusal to accept this type of material would create more of a hardship to mailers, requiring its analysis or use, than the limited risk it may present to employees."

So, the message is clear to the window clerks, even though Publication 52 allows retail clerks to seek advice from local management or from Regional Mail Classification Centers, the imperative to "move the mail" effectively negates this option.

One solution would be to require notification to the accepting facility of the arrival of any hazardous material, and to enforce that requirement.

Our National Agreement was amended in 1987 negotiations to strengthen on-the-job training of employees whose duties require the handling and/or transportation of hazardous items, as well as labeling of mail bags and the availability of personal protective equipment to employees exposed to spills and breakage of hazardous materials.

We asked for more, and more is required, but I have to say that the training, where it has taken place at all, is incomplete and inadequate. Let me illustrate with one example in Eugene, Oregon.

In March 1985, the employees were exposed to the fumes from a paint solvent that was circulated in the work areas by a painting contractor. Several employees became ill. In July 1986, a drum containing cresyllic acid ruptured in a mail truck. The ruptured drum was actually moved into the facility, where it stayed for several days. It took days to get a material safety data sheet from the shipper.

As it turned out, when it was received and analyzed by an APWU expert, the MSDS was inaccurate. The label on the package was destroyed, and was of no help in identifying the contents.

One hundred and twenty-nine postal workers were severely affected and were hospitalized with respiratory ailments and the like. They were sent to a USPS contract clinic, instead of a hospital which had experience in toxic exposure.

The medical diagnoses were less than adequate. In addition, no adequate follow-up medical surveillance has been done. Ultimately, on May 12, 1988, the Portland, Oregon Division issued revised Standard Operating Procedures for Hazardous Material Spills and Leaks. This procedure, by the way, is another problem with the USPS program to respond to hazardous spills and accidents. Each of 74 divisions, it appears, issues its own standard operating procedures.

We know of no centralized control or review. The training was never accomplished in Eugene. And I have never heard of a drill, like a fire drill, anywhere in the USPS system to test the response to an emergency hazard of this sort.

Sure enough, on June 3, 1988, another accident occurred in Eugene. A container of Toluene Ester Acrylic Sealer—we believe; we still don't have the report—spilled at the BMC in Seattle, contaminating the mail. The bulk mail center shipped the mail anyway and supposedly warned the Eugene office.

When the mail truck was opened, the fumes caused three postal workers to get sick. The response, as before, was "Keystone Kops." The best plan on paper is worthless without training and drills.

Until the USPS puts in place an adequate program to respond to toxic spills and accidents, they should not begin to consider carrying anything as dangerous as botulism and anthrax agents.

There is yet another problem with the USPS's toxic mail rules, namely there is no effective program to police compliance. The only way we find out whether a given shipment is properly labeled and packaged is when it breaks. The Postal Service has verbally accepted our proposal and hopefully, inspection will begin in the very near future.

Mr. Chairman, all this regulation-by-reference creates the additional problem that no one is really in charge. Who polices compliance with DOT or Public Health Service regulations? The USPS? The DOT? HHS? As in the case of labeling, the USPS relies completely on voluntary compliance.

The only penalty for willful non-compliance is a $1,000 fine and a year in prison. The annotations to U.S. Code Section 1716 show no reported case of a prosecution for failure to follow USPS regulations.

Perhaps the criminal code is too heavy-handed an instrument to secure compliance. A system of civil fines may be better. The USPS

could require a permit to ship such matter, and should require advance notice before it is presented for acceptance into the mail stream. Certainly, the USPS must pay more attention to assuring compliance with its regulations. The potential consequences of noncompliance are just too great.

Mr. Chairman, I would like to add one last observation. If the Army went to a private carrier to ship its biological weapons, you can be certain that the price would be high indeed.

The USPS, on the other hand, charges one rate for the same service, regardless of the contents of the package. I find it ironic that this Administration, which would privatize—I call if "profitize"—the USPS to allow cream-skimmers to carry cheap, safe mail still turns to the USPS when it wants to ship highly dangerous materials which would be otherwise too expensive to transport.

I will gladly try to answer any questions you may have. I do want to add, and I hope it is not offensive to anybody, but a further indication of a slovenly way to deal with these things was the testimony of the gentleman previously, the mail handler in Maryland. I have no doubt that he is interested in it and so on. But it seems to me that in assigning him to just look over the regulations and the means of dealing with such serious problems kind of understates anything, to put it mildly, and kind of reflects the fact that there is still no maturity in dealing in these areas.

As a matter of fact, some of the items I have here from the Postal Publication 52 in the Domestic Mail Manual says absolutely non-mailable items, explosives, ammunition, fireworks, matches, products packaged with poisonous compressed gas, liquid oxygen, Class A poisons, irritants, handguns, poisonous insects, mustard gas, poison gas, germicide, if it doesn't meet these requirements and the Postal Service feels it is inadequate, by all means the regulations should be very promptly corrected or revised.

And I certainly believe that this type of stuff should not be in the mails. It is a risk to the general population also.

Mr. McCloskey. Thank you very much, Mr. Biller, for an excellent statement. I really don't have any questions. I think some of your last comments go right to the point, given the testimony from Mr. Miss just before you and the concerns you so forthrightly stated.

Obviously, if the Post Office is going to continue to handle these materials, there needs to be better emergency follow-up and safety procedures. I think that point is very well taken. I do know, from having already read their testimony, that the Postal Service is sincerely concerned about this. I appreciate your being here today, sir. Thank you very much.

I am now going to call a two-person panel which I am sure will be very valuable: Mr. Dashiell from the U.S. Department of Defense, Director of Environmental and Life Sciences; and Dr. John W. McVicar, Director of Office of Biosafety, Centers for Disease Control of the U.S. Department of Health and Human Services.

Gentlemen, thank you for your patience. Please come up. Mr. Dashiell and Dr. McVicar, proceed as you would like.

STATEMENT OF THOMAS R. DASHIELL, DIRECTOR, ENVIRONMENTAL AND LIFE SCIENCES, U.S. DEPARTMENT OF DEFENSE

Mr. DASHIELL. Thank you, Mr. Chairman.

I have with me today Colonel David Huxsoll. Dr. McVicar and I agreed ahead of time he would go first and I will follow him.

Mr. MCCLOSKEY. Please proceed.

STATEMENT OF JOHN W. McVICAR, DIRECTOR, OFFICE OF BIOSAFETY, CENTERS FOR DISEASE CONTROL, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Dr. MCVICAR. Mr. Chairman and members of the subcommittee, I am Dr. John W. McVicar, Director of the Office of Biosafety, Centers for Disease Control (CDC). I am pleased to present this testimony on the subject of transporting biological materials and etiologic agents.

The Centers for Disease Control serves as the national focus for developing and implementing disease prevention and control measures as well as environmental health, health promotion, and education activities designed to improve the health of the people of the United States. Included in our mission are activities, including research, which identify, prevent, and control the spread of infectious diseases. Some of these activities involve shipping infectious materials. consistent with the mission of CDC, it is our policy to take the maximum precautions to protect the safety and health not only of all of our employees, but also the surrounding community, the environment, and the people of our Nation.

In 1971, the Food and Drug administration's authority for governing the interstate shipment of etiologic agents was delegated to the Centers for Disease Control. The Public Health Service Interstate Quarantine regulation (42 CFR, Section 72.25) was revised and became effective July 31, 1972. This regulation described packaging requirements; a special hazard warning label for the outside of the package, a system for telephone reporting damaged or leaking shipments of etiologic agents, and a system for responding to these reports. This regulation was revised, renamed the Interstate Shipment of Etiologic Agents (42 CFR Part 72), and adopted on August 20, 1980.

Materials known or presumed to contain a viable microorganism or its toxin, which may cause human disease, are subject to these packaging and shipping requirements.

In addition to etiologic agents, this regulation also requires that diagnostic specimens such as blood and urine and other biological products are subject to the packaging requirements described in 42 CFR, Part 72.2. Part 72.2 specifies that diagnostic specimens must be packaged ". . . to withstand leakage of contents, shocks, pressure changes and other conditions incident to ordinary handling in transportation." It is the sender's responsibility to provide packaging that meets these conditions. The etiologic agent hazard warning label is not required for shipments of these diagnostic specimens.

Specific instructions for packaging and shipping etiologic agents are found in 42 CFR Part 72.3. The figures attached to this statement illustrate packaging that complies with this regulation.

Mr. McCLOSKEY. Dr. McVicar, I have your statement here, but can I ask a question?

Dr. McVICAR. Surely.

Mr. McCLOSKEY. Evidently from your statement, the Centers for Disease Control have regulatory authority for all shipments in this area, whether it be DOD, private labs or whatever. Is that right?

Dr. McVICAR. Yes, sir. This authority was delegated to the Public Health Service and Centers for Disease Control and comes from our office.

Mr. McCLOSKEY. You have heard some of the previous testimony, like the mail handler here, and so forth. Why is there so much evident noncompliance?

Senator Levin states there is no real safety, oversight, or administrative function in the system here. What do you have dedicated to compliance in this area?

Dr. McVICAR. We don't really deal with the enforcement issues. Our agency is not a compliance-oriented agency. Our attornies tell us that this regulation comes under the general umbrella of the public health law in protecting the public health of the country and its citizens, and there are penalties that go along with this.

Mr. McCLOSKEY. Can we try this again now? Excuse me for not being an expert in the area; I have more to learn. In quoting you, "In 1971 the Food and Drug Administration's authority for governing the interstate shipment of etiologic agents was delegated to the Centers for Disease Control."

Now, you have authority for governing interstate shipment. Do you have authority without enforcement?

Dr. McVICAR. Our authority extends, as far as I know, to the development of the regulations.

Mr. McCLOSKEY. But you don't enforce the regulations?

Dr. McVICAR. No, sir, we do not.

Mr. McCLOSKEY. I think this is a big hole. Please proceed.

Dr. McVICAR. Let me return to the packaging and shipping of the etiologic agents—these agents are required to be shipped in a sealed primary container which is inside a second container that is filled with enough absorbent material to absorb all of the liquid in that primary container. The second container is then placed in a mailing tube or box with shock resistant packing material. The sealed box carries an etiologic agent sticker with a 24-hour telephone number to call should any breakage or leakage occur. The regulation also provides for those shipments containing certain dangerous organisms, such as Ebola virus, and the organisms that cause tularemia and plague, to be sent by registered mail, or by an equivalent system, which requires that the sender be notified when the package is delivered.

CDC has a packing and shipping unit that prepares shipments of etiologic, non-etiologic, and reference reagents. This CDC unit adheres to the regulatory requirements for packaging and shipping these materials. In the period January 1, 1987, through May 31, 1988, CDC shipped approximately 10,500 such packages from its Atlanta facilities. Fewer than 10 percent of these packages contained etiologic agents.

Currently CDC has three interagency agreements with the U.S. Army Medical Research Institute for Infections Diseases (USAM-

RIID) at Ft. Detrick for research on hemorrahagic fever viruses. These agreements support studies designed to improve methods of preventing and treating these diseases. During the 17-month period mentioned above, 17 packages were sent to USAMRIID. Four of these packages contained etiologic agents and were sent by a commercial overnight carrier. The 13 packages that contained other biological materials were shipped via the U.S Postal Service.

Under the Interstate Shipment regulation, CDC has a 24-hour telephone service to provide assistance if a package containing an etiologic agent becomes damaged or does leak. The required package hazard warning label carries the CDC telephone assistance number. A written record is kept of each call. During the last nine-year period, of the thousands of shipments each year, CDC logged an average of approximately 50 calls per year for damaged and leaking packages.

On the average, three of these calls per year were for packages containing etiologic agents that were actually damaged and leaking. These packages contained cultures of a variety of organisms [S. aureus, C. albicans, C. tetani, N. gonorrhea, E. coli, K. pneumoniae, Western equine encephalitis arbovirus, rabies virus, M. tuberculosis, S. pneumonia, Salmonella sp., Herpes virus, P. aeruginosa, H. ducreyi, P. vulgaris, Clostridium sp. and M. luteus). Of the etiologic agent packages that were reported to CDC as leaking, none resulted in a reported infection. The other packages were either damaged with no leaks, were "wet" with no damage or leakage, or contained only diagnostic specimens and no known etiologic agent cultures.

I might mention that these wet packages are a frequent cause of the phone calls, and more times than not this is leaking water from melting ice or condensation from dry ice.

In summary, many thousands of packages containing diagnostic specimens, test reagents, etiologic agents, and other biological materials are shipped safely through our postal system each year. Some of these packages do contain etiologic agents that are used in clinical test laboratories for quality control and identification purposes. Research laboratories use these cultures to develop vaccines, treatments, and diagnostic tests which aid in the identification and control of disease.

Mr. Chairman, we share your concern for the safety and health of postal employees. We believe that the record shows that adherence to the Federal packaging and shipping regulations of infectious materials has been effective in preventing the infection of these employees. We further believe that any action that would curtail the exchange of infectious agents between laboratories would seriously impede progress toward controlling and treating important human diseases.

Mr. Chairmen, this concludes CDC's prepared statement. I will be glad to try to answer any questions that you or other members of the subcommittees may have. Thank you.

Mr. McCLOSKEY. Would you like to do that after Mr. Dashiell's statement?

Dr. McVICAR. Perhaps we should wait until Mr. Dashiell finishes.

[The following response to written questions was received subsequent to the hearing:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta GA 30333

September 9, 1988

Frank McCloskey, Chairman
Subcommittee on Postal Personnel
and Modernization
Room 603, House Annex #1
Washington, D.C. 20515

Dear Mr. McCloskey:

In response to your letter of August 16, enclosed are the answers to your questions concerning the shipment of etiologic agents.

Please contact me if you have further questions.

Sincerely yours,

John W. McVicar, D.V.M.
Director
Office of Biosafety

Enclosure

Questions for the Centers for Disease Control
From Representative Frank McCloskey

1. Q What specifications were used in determining packaging requirements in the 1980 revision of the packaging regulations?

   A The "specifications" in 42 CFR Part 72 - Interstate Shipment of Etiologic Agents are largely generic. Specifications for packaging materials are found in DOT regulations (49 CFR Parts 100-199).

2. Q You mentioned that it is the sender's responsibility to provide packaging which meets these requirements. How do you verify that the packaging meets the specifications?

   A Verification of packaging before the shipment is made is not possible. However, if a package of diagnostic specimens is found to be leaking at anytime during shipment, and the conditions were not judged to be extreme, the packaging would not have met the requirements of Section 72.2. The requirements of Section 72.3 (minimum packaging requirements for etiologic agents) can be verified by the receiver at the time the package is received. In actual operation, the packaging is self-regulating. The shipper has a vested interest in getting the material to its destination in the best possible condition.

3. Q You also stated that diagnostic specimens must be packaged to "withstand ... conditions incident to ordinary handling in transportation." Does the same language apply to etiological agents? (What consideration has been given to extraordinary conditions such as car wrecks, etc?)

   A The requirements of Section 72.3, for etiologic agents, exceed those of 72.2, for diagnostic specimens; therefore, packages prepared following these requirements would be expected to withstand such conditions. Experience over the years has shown that this type of packaging is able to withstand extreme conditions of handling. We frequently get calls concerning packages that have been extensively damaged while the inner containers (primary and secondary) have remained intact and have not leaked. Secondary containers can withstand forces that dent and crumple them and still protect the contents.

4. Q In your statement you indicated that a written record is kept of each call coming into CDC. Does this mean every call you receive or every call in which the package is determined to have been damaged? (I ask this question because prior to the hearing my staff spoke to a member of your staff and his account of the number of phone calls that CDC receives does not coincide with your testimony.

A The label required under Section 72.3 directs those handling the package to call CDC "in case of damage or leakage". The calls that we receive actually cover packages that are visibly damaged or that have the appearance of leaking. Frequently in the latter case, the contents are not actually leaking but the package is wet because of melting ice or condensation from dry ice used to preserve the material. Sometimes the package is wet from external sources but may appear to be leaking. We record each of these calls whether or not actual leakage has occurred. Some members of my staff who were only indirectly involved with this issue were not aware of the results of our examination of the damaged package files. The figure provided to you by one of our staff represented his best estimate.

5. Q What type of education program has CDC conducted to educate the medical community about the packaging requirements?

A Copies of the regulation have been widely distributed since it was published in the Federal Register. We have also distributed a booklet describing the packaging process (copy attached). In addition to our efforts, the regulation is either referenced or printed verbatim in a number of widely distributed manuals and guidelines including:

"Guidelines for Research Involving Recombinant DNA Molecules" developed and distributed by the National Institutes of Health;

"Procedures for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents" developed by the National Committee for Clinical Laboratory Standards with help from CDC staff;

"Publication 52, Acceptance of Hazardous, Restricted or Perishable Matter" published by the U.S. Postal Service for the use of its employees;

"Biosafety in Microbiological and Biomedical Laboratories" developed jointly by CDC and NIH.

In addition, our staff has made numerous presentations at national and regional meetings, workshops, and training courses, and we are constantly on call to answer questions and provide guidance to shippers, handlers, and receivers of biological materials.

6. Q There appears to be a lot of confusion currently on what needs a red CDC label and what does not. In view of the increased number of blood specimens being sent these days with the possible HIV infection, has CDC sent out information reiterating the regulation contained in 42 CFR Part 72?

A We are currently reviewing the regulation and have a draft of proposed revisions intended to clarify it.

7. Q Do you have any recommendations to improve the present system to ensure the health and safety of postal workers and the public?

A Our recommendations to clarify the current regulations are noted in the attached draft of proposed revisions to those regulations.

8. Q Although individuals in the medical community are apt to stress that no accidents that have infected anyone have occurred when mailing etiologic agents, the three leaking packages to which you refer in your statement show that there is a possibility for damage under the current system. Granted this is a small number of incidents, however, I do not feel that it should be downplayed. What are your comments?

   A We are most assuredly concerned with the health and safety of the postal workers and the public. The present system, although not perfect, has significantly reduced the risk of infection from shipping etiologic agents. We must strive to reduce the perception of risk. A package of etiologic agents may be wet for a number of reasons or noninfectious material may sometimes leak and we understand that postal workers are not in a position to make risk assessments. We must, therefore, continually work to improve the system. We do not believe that the Postal Service's proposed rule is justified. The proposed rule has little or no potential for positively affecting the health of postal workers and considerable potential for negatively influencing the transportation of materials essential to protecting the health of our citizens.

9. Q Who do you feel should enforce the Public Health Service regulations on packaging and transporting etiologic agents?

   A I strongly believe that the regulation would best be enforced by the Postal Service. Postal inspectors would be on or close to the spot should an incident occur and should be able to take immediate action. The PHS would be available for consultation and advice. We rely now on local health departments to provide assistance when needed and help should continue to be available.

Mr. McCLOSKEY. Mr. Dashiell.

STATEMENT OF THOMAS R. DASHIELL

Mr. DASHIELL. I am pleased to be here today to provide information on our Biological Defense Research Program and, more specifically, how that program relates to the subject of the hearing, transportation.

I have a prepared statement which I will submit for the record and I will try to summarize that for you.

A critical point in understanding the Biological Defense Research Program is our national policy. This country unilaterally renounced biological weapons in 1969 and destroyed all stockpiles of biological and toxin materials and all associated munitions. Subsequently, we led the negotiations and became a party of the Biological Weapons Convention that was signed in 1972 and ratified in 1974 by the Senate.

Our Biological Defense Research Program and this nation are in full compliance with all provisions of the convention. We have no biological weapons. We do not make biological agents. The Biological Defense Research Program is presented very openly to the Congress in an unclassified report each year.

Detailed accounts are provided to the public. I provide approximately 50 copies of that same annual report to interested members. In addition, scientific papers are published in scientific journals. Approximately 150 papers were available last year out of Colonel Huxsoll's laboratory.

Biological agents are not militarily unique. They have been the cause of disease in man and animals throughout most of recorded history. In fact, many U.S. Department of Agriculture and Public Health Service Laboratories, along with state and local laboratories conduct continuing surveillance for the incidence of the same diseases and maintain diagnostic capabilities for a number of diseases such as anthrax, brucellosis, plague, tularemia, Q fever, staphylococcal enterotoxemia and botulism.

These diseases are all endemic to the United States. They are in fact naturally occurring pathogens which cause disease in this country and are monitored by the state and national public health officials. The same holds true for toxins which occur in nature as a by-product of many organisms. Within the United States, transportation of potentially hazardous and infectious materials and toxins, termed "etiologic agents", is highly regulated.

That has been described to you by Dr. McVicar and I will not cover that at this point. Shipment of etiological agents is designed to meet two objectives which I think the committee should know. First, it is vital to both the shipper and the receiver that the specimens and cultures be delivered intact and in viable condition if they are living materials. Second, the carrier must be assured that there is only an extremely small and acceptable risk to those persons who handle the packages in transit, as well as non-laboratory personel within the sending and receiving organizations.

The Department of Defense investigation of safe means of packaging biological specimens and cultures was initiated over 30 years ago at Fort Detrick, Frederick, Maryland.

Research on packaging involved field tests of various combinations of inner and outer containers to determine if leakage to the outside environment could be totally prevented. Tests included the standard drop tests from four, ten and eventually 40 feet to concrete; penetration tests with steel rods; crushing tests; wetting tests where boxes were soaked in a shower prior to the drop and penetration tests.

The packaging configurations ultimately met all of these tests without failures and were approved for shipments of up to one U.S. gallon. These reports have been made available to the committee for review, and that data still provides a basis for our present standard. I will not go through how we package an etiological agent at this point in time. That will be described by Colonel Huxsoll in detail.

To address the question of the actual number and frequency of shipments of these regulated materials in the conduct of the Biological Defense Research Program, USAMRIID, the largest and most active primary research site serves as a good example. In 1987 USAMRIID made 48 shipments of etiologic agents, all by private courier service, none of which were biosafety level 4, the most hazardous material, an average of approximately one per week.

The mean size of a shipment was 6.9 milliliters or about one and one-third teaspoons. The median size of the shipment, that is, the size in the middle, was 2 milliliters, less than one-half of a teaspoon. USAMRIID's standard operating procedures require that three professional employees: the investigator, the division chief and the safety officer, must concur on the classification of the material to be shipped.

DOD uses overnight express package service for this program. The choice of this mode of shipment is for reasons of greater certainty of timely arrival of the specimen. The air carriers provide excellent tracking and documentation of a shipment, appropriate handling and timely delivery.

In conclusion, the question of the safety of the shipments of biodefense-related materials is a very reasonable one. The packages, in the amounts which we are shipping, have been performance tested and are literally able to survive an aircraft or highway crash.

The overwhelming majority of the shipments contain very small amounts, usually less than a teaspoonful, and all of our shipments are regulated by the same Public Health Service and Department of Transportation requirements that apply universally throughout the United States.

Finally, however, we recognize the concerns of the public as expressed by the committee in the testimony I have shared with you today. I must point out that we feel DOD poses no unique problems that are not shared by the medical and agricultural research communities.

We do not ship weapons. We do not possess any weapons. Only small quantities of research materials necessary to develop effective defense measures are involved in the current program. We have conducted a comprehensive review of policy and procedures for the shipment of etiologic agents to identify areas which we feel could benefit from improved administrative control.

Accordingly, we are implementing a series of procedural and administrative provisions to further ensure that biological materials and any future shipments originated by the Department are under the following positive controls. One, all military facilities conducting biological defense research work will continue to maintain full compliance with the CDC–NIH guidelines. Further, any DOD-sponsored research will also be required to maintain compliance with these guidelines.

Two, contract clauses will specify that all biological defense research contractors who provide etiologic agents as deliverables will pack and ship all materials in accordance with Title 42 CFR 72 and all other applicable state and local laws and regulations. To conform to DOD procedures, all secondary containers will be sealed with a crimped lid. Three, DOD will continue the present practice of shipping all etiologic agents by private carrier. This policy will be extended to include biological defense research contractors who provide etiologic agents as deliverables.

Last, the most hazardous biological materials, which are biosafety level 4 etiologic agents, are presently handled by DOD only at USAMRIID and are identical to those being studied in non-DOD labs. The shipment of BL–4 agents is extremely rare, the last one being in 1985. However, recognizing the sensitivity of DOD programs, if a BL–4 agent is shipped, it will be hand-carried by government courier under the immediate supervision of a responsible individual.

This individual will monitor all aspects of the shipment, ensuring that required transfers have been completed and documented and final receipt has been accomplished and acknowledged.

We believe that adding these additional controls to the already rigorous regulations will provide the peace of mind desired by the public in shipment of biological materials without adding an extreme burden on the many other parties who ship these and similar materials throughout the country and the world.

I would like at this time to have Colonel Huxsoll describe the packaging for you and the committee.

[The statement of Mr. Dashiell follows. Also included are response to written questions.]

DEPARTMENT OF DEFENSE
STATEMENT ON
TRANSPORTING BIOLOGICAL MATERIALS

BY

MR. THOMAS R. DASHIELL
DIRECTOR, ENVIRONMENTAL AND LIFE SCIENCES

TO

THE SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION

OF THE

COMMITTEE ON POST OFFICE AND CIVIL SERVICE
UNITED STATES HOUSE OF REPRESENTATIVES
100th CONGRESS, SECOND SESSION

JUNE 23, 1988

I am pleased to be here today to provide information on the Department of Defense biological defense research program and specifically how that program relates to the subject of this hearing, transportation of biological materials through the US postal system. I will not consider the transportation of other similar materials which involve clinical or diagnostic specimens from hospitals or clinical laboratories to analytical facilities --many of which are shipped in the same manner.

Before I discuss transportation, I would like to briefly review the objectives of the biological defense research program. It has a two-fold objective: first, to provide an adequate level of protection to US forces against the use of biological and toxin agents and second, to provide a deterrent to any potential use through a visible and effective defensive posture. The program to meet this objective is largely medically oriented and comprises medical prophylaxis and therapy, decontamination, early detection and identification of disease agents, and protective clothing and shelters. Specifically, medical defense against biological agents includes research on vaccines, toxoids, antitoxins, drugs, and methods for rapid diagnosis, agent identification and patient decontamination.

A critical point in understanding the biological defense research program is our national policy. This country unilaterally renounced any use of biological and toxin weapons in

1969 and after filing environmental impact statements, destroyed all stockpiles of biological and toxin agents and all associated munitions. Subsequently, this country led the negotiations and became a party to the Biological Weapons Convention that was signed in 1972 and ratified by the Senate in 1974. Our biological defense research program and this nation are in full compliance with all provisions of the convention.

The biological defense research program (BDRP) is conducted by in-house laboratories and a large part, about 60 percent, is conducted under contract to universities, other government agencies and industrial organizations. Technical aspects of the program are unclassified and detailed accounts are provided to the Congress and the public each year. In addition, scientific papers are published in peer-reviewed scientific journals. Each year approximately 150 publications are available to the public from the principal laboratory, the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). Our program is reviewed by a wide variety of outside scientists for technical content and we sponsor a number of international conferences. We fully comply with all regulatory agency requirements in the conduct of the program.

Biological agents are not militarily unique. They have been the cause of disease in man and animals for most of recorded history. As such, their epidemiology has been studied for

decades. Anthrax, an acute disease caused by Bacillus anthracis normally transmitted by contact with tissues of infected animals or contaminated animal products, is a disease well-documented in antiquity. The Bible contains a vivid description of the fifth and sixth plagues of Egypt at the time of Moses. These plagues, that affected both cattle and man, were most certainly caused by anthrax. Virgil, the Roman agriculturalist, described a pestilence in sheep that was undoubtedly anthrax.

It may be of interest to know that the germ theory was developed with work on anthrax. In Germany, Dr. Robert Koch studied anthrax and in 1876 he isolated a single type of bacterium in mice from sheep that had the disease. He then introduced the disease from the mice back into sheep. This was the first experimental proof that a specific organism caused a specific disease. We still use Koch's postulates today. They originated with work on anthrax, a disease caused by an organism generally accepted as a potential biological warfare threat.

Many US Department of Agriculture and Public Health Service laboratories, along with state and local laboratories, conduct continuing surveillance for the incidence of disease, and maintain diagnostic capabilities for diseases such as anthrax, brucellosis, plague, tularemia, Q fever, staphylococcal enterotoxemia and botulism. These diseases are all endemic to the US.

Although these particular etiologic agents are sometimes referred to as "classical" biological warfare agents, they are in fact, naturally occurring pathogens which cause disease in this country and are monitored by our state and national public health officials. As a consequence, there is daily nonmilitary traffic in diagnostic specimens, live vaccines and stock cultures. While these pathogens are of considerable defensive interest to us, they are neither unique to the military nor under the control of the military.

The same holds true for toxins which occur in nature as by-products of many organisms. A common food-borne illness, for example, is caused by a toxin produced by the ordinary bacterium, Staphylococcus aureus. Over the past 15 years, naturally occurring toxins have been routinely used throughout the world's research community in neuroscience, pharmacology and toxicology. For example, botulinum A toxin is used in the treatment of certain eye diseases in man and targeted toxins are being developed for the treatment of cancer. These materials are of great value in research and treatment of many significant human health problems. Consequently, toxins are widely available from biomedical and chemical supply firms and are synthesized in numerous laboratories. These toxins are routinely shipped among suppliers and investigators throughout the world.

Within the biological defense research program there is the need to transport laboratory samples of biological materials. A detailed description of the shipment of etiologic agents is provided in the Draft Programmatic Environmental Impact Statement (Appendix 2) filed in May 1988. I will summarize that information for the committee.

Within the US, transportation of potentially hazardous infectious materials and toxins, termed "etiologic agents," is highly regulated. Title 42 of the Code of Federal Regulations (CFR) Part 72 establishes the pertinent regulations which uniformly apply to all military, government and non-government organizations.

Regulations on the shipment of etiologic agents are designed to meet two objectives. First, it is vital to both the shipper and the receiver that the specimens and cultures be delivered intact, and in viable condition if they are living materials. Second, the carrier must be assured that there is only an extremely small and acceptable risk to those persons who handle the package in transit. This latter consideration includes the general public, as well as those non-laboratory personnel within the sending and receiving organizations who must handle the package when it is not within the laboratory itself.

The regulations at 42CFR 72, published by the Public Health Service, provide for three types of control of these etiologic agents. First, the bacteria, fungi, viruses and rickettsia that are subject to these requirements are listed. Second, the actual packaging and shipping requirements are specified. These packaging requirements reflect closely the requirements of the US Department of Transportation (DOT), which describe them in detail at 49CFR 173. Third, a list is given of those etiologic agents for which shipment by "registered mail or equivalent system" is required.

Many of the organisms used within the biological defense research program are classified as etiologic agents for the purposes of shipment and several are identified on the list of organisms requiring shipment by "registered mail or equivalent system." The regulations also specify procedures for notification of the Center for Disease Control in the event that any package bearing the "Etiologic Agents/Biomedical Material" label is damaged or shows evidence of leaking, or in the event that a sender does not receive a notification of delivery within five days following anticipated delivery of the package.

Army investigation of safe means of packaging biological specimens and cultures was initiated over 30 years ago at Ft. Detrick, Maryland. Research on packaging involved field tests of

various combinations of inner and outer containers to determine if leakage to the outside environment could be totally prevented. Tests included standard drop test from 4, 10 and eventually 40 feet to concrete; penetration tests with steel rods; crushing tests; and wetting tests where boxes were soaked in a shower prior to the drop and penetration tests. The packaging configurations ultimately met all of these tests without failures, and were approved for shipments of up to one US gallon (3787 ml) per container. These data still provide a basis for our present standards.

Etiologic agents that we ship are packed in a primary container, consisting of a water tight sealed tube or vial, inside the laboratory. The outside of the tube or vial is decontaminated with disinfectant. The primary container is surrounded with sufficient absorbent material to absorb the entire volume of the sample which is then placed inside a metal can, the secondary container, which is then sealed with a crimped lid. This secondary container is then surface decontaminated and passed out of the laboratory to a shipping area. Note that the crimp sealed secondary container exceeds the regulations for domestic shipment, which specify a screw capped metal container sealed with waterproof tape. The secondary container is placed in a snugly fitting cardboard tube or in another metal can (tertiary container). If the secondary container is packaged in a metal can as the tertiary container, all empty space within the

tertiary can is packed full with shock absorbent material. For unrefrigerated shipment, the tertiary container can be used as the shipping container. The tertiary container is screwed shut, or, in the case of a metal can, crimped or spot soldered. In practice, the tertiary container is packaged in a fiberboard or equivalent box, surrounded by shock absorbent material and shipped in this fourth container.

For shipment of refrigerated or frozen materials, the tertiary container is placed in a styrofoam box and taped securely in place or braced with cardboard inserts. Dry ice or "blue ice" coolant is then packed around the tertiary container. The styrofoam box itself constitutes a fourth container.

The styrofoam box is placed in a snugly fitted cardboard or fiberboard box, which is the fifth container and is the outermost shipping box. The Health and Human Services Standard Form 420, etiologic agent shipping label, is affixed to this outermost box, along with the standard shipment information.

What is the actual number and frequency of shipments of these regulated materials in the conduct of the BDRP? The activities of USAMRIID, the largest and most active primary site in the BDRP, serve as a good example. In 1987, USAMRIID made 48 shipments of etiologic agents, all by private courier service, none of which were biosafety level 4 (BL-4)agents, to other

institutions and organizations, an average of approximately one per week. Thus, BDRP-associated shipments of etiologic agents are actually rather infrequent even in the most active organization.

The mean size of a shipment was 6.9 ml, or about one and a third teaspoons. The median size of a shipment, i.e. the size in the middle-24 larger and 24 smaller, was 2 ml, less than one-half of a teaspoon. USAMRIID standard operating procedures also require that three professional employees - the investigator, the Division Chief and the Safety Officer - must concur on the classification of the material to be shipped.

Even though shipment of cultures and specimens through the US Postal Service is legal, and is regularly used by many military and civilian clinics and laboratories if the sample is stable for several days, DoD practice is to use overnight express package services for this program. The choice of this mode of shipment is for reasons of greater certainty of timely arrival of the specimens. The air carriers provide excellent tracking and documentation of a shipment, appropriate handling, and timely delivery.

In conclusion, the question of the safety of shipments of BDRP-related cultures and specimens is a reasonable one. The shipment of etiologic agents has been regulated closely by the PHS and the DOT, as well as by DoD and the Army. Packages,

especially those used for the very small vials in which frozen cultures are shipped, are literally able to survive an aircraft or highway crash, and have been performance-tested for this capability.

The overwhelming majority of shipments contain very small volumes, usually less than a teaspoonful. USAMRIID and the other primary and secondary sites are all regulated by the same PHS and DOT requirements that apply universally throughout the US. Present standards ensure that the potential for hazard to the public arising from shipment of etiologic materials such as those used in the BDRP is miniscule.

Finally, however, we recognize the concerns of the public as expressed by this committee. I must point out that the DoD poses no unique problems not shared by the medical and agricultural research communities. We do not ship weapons or similar items because we possess none. Only small quantities of research materials necessary to develop effective defensive measures are involved in the current program. To add to the many safety features I have already described, we have conducted a comprehensive review of policy and procedures for the shipment of etiologic agents to identify areas which could benefit from improved administrative control.

Accordingly, we are implementing a series of procedural and

administrative provisions to further ensure that biological materials and future shipments originated by the Department are under the following positive controls:

1. All military facilities conducting biological defense research work will continue to maintain full compliance with CDC-NIH guidelines. Further, DoD sponsored research at contractor facilities will also be required to maintain compliance with these guidelines.

2. Contract clauses will specify that all biological defense research contractors who provide etiologic agents as deliverables will pack and ship all materials in accordance with Title 42 CFR 72 and all other applicable state and local laws and regulations. In addition, to conform to DoD procedures, all secondary containers will be sealed with a crimped lid.

3. DoD will continue the present practice of shipping all etiologic agents by private carrier. This policy will be extended to include biological defense research contractors who provide etiologic agents as deliverables.

4. The most hazardous biological materials, which are biosafety level 4 etiologic agents, are presently handled by DoD only at USAMRIID, and are identical to those being studied in non-DoD laboratories. The shipment of BL-4 etiologic agents by DoD is rare, the last being in 1985. However, recognizing the sensitivity of DoD programs, if a BL-4 agent is shipped, it will be hand carried by government courier or under the immediate

supervision of a responsible individual. This individual will monitor all aspects of the shipment, ensuring that required transfers have been completed and documented and final receipt has been accomplished and acknowledged.

We believe that adding these additional controls to the already rigorous regulations will provide the peace of mind desired by the public in shipment of biological materials without adding an extreme burden on the many other parties who ship these and similar materials throughout the country and the world.

QUESTION: What private courier service(s) does USAMRIID use for BL-4 agents? How often do you send BL-4 agents from lab to lab? Have any accidents ever occurred with this courier, regardless of what agent was being shipped?

ANSWER: Through the Fort Detrick Transportation Office, USAMRIID ships etiologic agents air express. The most frequently used provider of this service has been Federal Express. BL-4 agents are sent from USAMRIID only rarely; the last such shipment was one sent in 1985. Current policy is that any shipment of a BL-4 etiologic agent will be hand carried by government courier or under the immediate supervision of a responsible individual. (There are a limited number of laboratories in the western world equipped with the proper facilities and equipment for handling BL-4 agents.) We know of no accidents involving USAMRIID shipments through Federal Express, regardless of the agent being shipped.

QUESTION: It is my understanding that just a few milliliters of several viable substances are of sufficient toxicity to endanger large numbers of people. Isn't the amount of the substances irrelevant in considering the danger of the material being shipped?

ANSWER: The amount of material being shipped is very important in determining the danger. In order for an etiologic agent to present a danger to a person handling a shipment, that person must receive an infectious dose by inoculation, ingestion, inhalation, or contact with a mucous membrane. It is true that in a labratory, a few milliliters of an etiologic agent properly disseminated may be sufficent for infection of a few expermental animals. However, extensive models for weapon systems show conclusively that relatively large quantities (pounds or gallons) of almost all recognized etiologic agents are required to infect any large number of people even when properly disseminated. In addition, the extremely small quantities shipped in the research program are not designed to be effectively disseminated and would generally only pose a hazard to an individual through direct contact. Properly packaged etiologic agents severely minimize the risk of exposure of individuals to any of the routes described above.

QUESTION: Your statement indicates biological agents are not unique. This does not take away the need to insure that these agents are transported safely. Do you believe that the military has a responsibility to ensure that the biological agents it sends and receives are transported safely? Who at DOD is accountable for safety? Who within the BDRP labs?

ANSWER: The DoD recognizes that their responsibility is to meet or exceed regulations and guidelines which assure the safety of all etiologic agent shipments. It has cooperated for many years in the development and testing of packaging standards to ensure safe shipment. Safety of shipments at DoD is monitored by the Director of Safety and Occupational Health Policy. Probably of more importance are the laboratory personnel who conduct the research. Within a BDRP laboratory, military or contractor, the laboratory worker, principal investigator, safety officer, and the Laboratory Commander or equivalent all share the responsibility for assuring safety of etiologic agent shipments.

QUESTION: One of the objectives which you have stated DoD mailing regulations attempt to meet is that the carrier is assured that there is "only an extremely small and acceptable risk" to carriers and the general public. By what calculus is this extremely small risk determined?

ANSWER: The Department of Defense adheres to regulations issued by the Public Health Service and the Department of Transportation. Our packaging configurations exceed these regulations in many aspects. These packaging configurations have been tested extensively under conditions that far exceed what would normally be expected in ordinary handling by the carrier or in a transportation accident. No risk assessment can ensure 100% safety, however, the extensive testing and the shipment history provide extensive evidence of "an extremely small and acceptable risk" to carriers and the general public. There are no documented instances of a postal worker, commercial carrier, or a member of the general public becoming infected or adversely affected by a properly packaged etiological agent shipment. Even with this proven record, we recognize that there is always some small unquantifiable risk associated with such shipments and we will continue to work to improve procedures and packaging requirements.

QUESTION: You state that the sender is to notify CDC when notification of delivery is not received within five days. How often has DoD contacted CDC for late deliveries? What procedure is followed to ensure receipt? What occurs after CDC is notified about a late or missing package?

ANSWER: The requirement to notify the CDC if a shipment is not received within 5 days of anticipated receipt is specified in the USPHS requlation 42 CFR Part 72, for those etiologic agents requiring shipment by "registered mail or equivalent." The DoD has not had occassion to contact CDC for any late deliveries. DoD did notify CDC regarding one Federal Express (not USPS) shipment which arrived in a timely manner but which did not contain the material requested. The "registered mail or equivalent" system provides an audit trail for ensuring receipt. Respectfully suggest that CDC be queried regarding the procedures implemented after receiving notification of a late, missing or leaking package.

QUESTION: What are the criteria for determining if metal or cardboard is used as the tertiary container?

ANSWER: The selection of metal or cardboard as a teritary container is based on operational criteria such as whether the shipment requires chilling with dry ice or refrigerant packet, and the size and configuration of the secondary container. Current DoD policy requires that the secondary container always be a metal can with a crimp-sealed lid.

QUESTION: Your testimony describes a "comprehensive review of policy and procedures for the shipment of etiologic agents which could benefit from improved administrative control." Has this review been completed yet? Can you provide me with a copy of your final report?

ANSWER: The review is a continuing process and a final report has not been issued. Anticipated revisions in CDC, USPS and DOT regulations, as well as pending development of an Army Biological Safety Regulation, must be considered before a final position is issued. The findings of the review to date were provided in the prepared testimony. The review noted is similar to that conducted by the regulatory agencies to insure that only the safest methods of packaging and control are used by all parties.

QUESTION: Do labeling requirements mandate the naming of the etiologic agents in the shipping container? Why and why not?

ANSWER: Labeling requirements do not mandate naming of etiologic agents on the outermost shipping container (where the Etiologic Agent/Biomedical Material label is located). Specimens are routinely labeled on their primary containers, and the CDC-NIH guidelines specify labeling with identification of the etiologic agent on the outside of the secondary container. IATA and other international and aeronautical regulations require that descriptions of material being shipped appear on shipping forms/bills of lading that are included in between the secondary and tertiary containers and are affixed to the outermost shipping containers. For the purposes of domestic mailing, providing the name of a given etiologic agent would not necessarily be meaningful to individuals not trained or educated in the appropriate field of microbiology, virology, etc. The point of the generic etiologic agent label, and of the definition of an etiologic agent, is that a potential hazard in the case of an accidental significant exposure exists regardless of the specifics of the agent in question.

QUESTION: How old are the regulations governing the transportation of etiologic agents? Have they been revised in any way to guard against possible terrorist interception of these agents?

ANSWER: Regulations governing the shipment of etiologic agents have their origins in testing and standards developed in the 1950's. The Public Health Service Interstate Quarantine regulation (42CFR, Sec 72.25) was effective July 31, 1972. The Public Health Service Regulation 42 CFR Part 72, "Interstate Shipment of Etiologic Agents", was last formally revised in 1980. The CDC is currently undertaking revision of this regulation. The Department of Transportation also is planning revision of its regulations at 49 CFR Parts 172 and 173, which pertain to hazardous materials and etiologic agents. It is our understanding that the Postal Service is planning analogous revisions to the Domestic Mail Manual. None of these regulations specifically address "terrorist interception", since that issue is properly addressed under other provisions of Postal Service and DOT regulations. At this time the threat of terrorist seizure of properly packaged materials is believed to be minimal since all of the materials are available from other sources. Should a terrorist attempt such a seizure, he would become an immediate target of appropriate authorities, obviously not a desirable outcome from a terrorist perspective.

QUESTION: Your statement says, "The air carriers provide excellent tracking and documentation of a shipment, appropriate handling and timely delivery." Does the DoD do any tracking, or is it only the air carriers that perform this function?

ANSWER: The responsibility for any shipment entered into any legitimate transportation traffic, be it the U.S. Postal Service or an air carrier, is vested with that carrier until such time as the shipment is delivered to the addressee. In the case of shipment of etiologic agents, such materials are generally sent in response to a specific request, and the sender and receiver are in communication regarding the shipment. The chain of custody of any shipment during its transit from origin to destination is through the carrier. The carriers provide an excellent record, and DoD sees no need to duplicate this function.

Mr. MCCLOSKEY. Please proceed. Thank you.

Colonel HUXSOLL. Thank you, Mr. Chairman. I would like to underscore a couple things that Mr. Dashiell mentioned. That is the nature of the organisms. We have been hearing a lot of testimony today about bombs and weapons and biological warfare agents. We possess none of those. What we possess are organisms that are no different than what you would find in any other research laboratory charged with the same mission, developing medical defense against a number of these different diseases.

So I am going to make that perfectly clear, and it also reflects the size of the shipment and that is usually very, very small. All of our shipment is in strict compliance with the Federal Code. I would like to just walk through that.

This is the quantity of material that we usually ship. You can see it there, a small amount of pink material, 2 ml. in a plastic vial. It contains a screw cap lid which has a gasket in it to assure that it does not leak. In addition, we wrap this with a piece of parafilm to again assure that it does not leak.

This goes into a zip lock bag, as such, and it is then placed into the secondary container, as such, and it is packed in the bottom, in the top and around the side with absorbent material in sufficient quantity to absorb the entire contents of the initial vial, the primary vial, should it leak.

At USAMRIID we actually can this. This lid goes on the top of that can and goes into a canner and when it comes out of the canner, it looks like a can of beans that you would buy in the local supermarket, but without the label.

Mr. MCCLOSKEY. You might want to hold that up so the people in the back can see.

Colonel HUXSOLL. We can even pass it around if people would like. The secondary container then goes into the tertiary container. An additional packing material is placed in the bottom, on the top, and around the sides, and this serves to absorb the shock. It is then secured with a screw cap lid cap. If I can take some of my paraphernalia out of here so I can get on with the packing process.

Most of our shipments are made with agents, organisms that require cooling or preservation with the use of ice, dry ice. We then place some dry ice in the bottom of the shipping container. This tertiary container is secured as such, placed inside the styrofoam box. A piece of cardboard serves to stabilize the tertiary container.

Additional dry ice is added, and I think the fact that we have to ship these cooled or on dry ice reflects the lack of stability of many of these agents. If we didn't keep them cold or we didn't send them frozen in a preserved frozen state, they would not survive even the short-shipment. The cover is then placed on top. The packing slip goes on top of that. It is then closed, taped and on the top goes the label indicating that there is an etiologic agent inside.

I think that that has been already demonstrated. Now, I would like to point out a couple of other things that we have recently instituted. According to the code, you can ship an etiologic agent as such. But we require often times some kind of a coolant. Therefore, the label and the etiologic labeling goes on the outside of this container. If it were to be shipped like that, the person would know immediately that he is dealing with an etiologic agent.

In this case, it goes on the outside of this container. In reviewing the procedure, we feel it might be important to add those labels to other containers. Should something happen that the outside container would be destroyed, which I believe is highly unlikely, they would get down to the next layer, and they would then see they are dealing with an etiologic agent. So we have changed our procedure to include that as well.

If we do not require shipping of the agent in a frozen or refrigerated state, our procedure at USAMRIID is to use this same shipping container, the same box, place this down in here and put styrofoam chips around the whole thing to fill it. Therefore, every shipment that goes out of USAMRIID is in this kind of a container. It becomes standard. It becomes uniform.

All of our shipments go out air express or federal express. We do that for the reasons stated by Mr. Dashiell. Thank you very much. If there are some questions, I would be happy to answer them.

Mr. McCLOSKEY. Gentleman, could we have 10 or 15 minutes of discussion? While I realize that we are not going to resolve this, I might say we will have numerous written questions for the record to you. If you can take the time and respond in a reasonable amount of time, I would appreciate it.

Now, you mentioned procedures, Colonel, for shipping from Fort Detrick. How about other military facilities or other facilities shipping to Fort Detrick? Are they required to do such?

Colonel HUXSOLL. They are required to follow the Federal Code like anybody else who puts something into interstate shipment.

Mr. McCLOSKEY. Okay. Again, we had some earlier testimony, which I will be referring to again today and in later communications, as to enforcement of regulations. I know there is good will and scientific and environmental concern as to all practices and procedures.

We heard testimony earlier today—and I think you were here for that testimony—from a postal employee who had the unfortunate experience of having a dead flu virus of some sort in his hands and at the time not knowing what it is. He is still with us, and he gave us additional information.

He was working yesterday and he had a container marked biohazard that did not meet any of the requirements that you are talking about today. This was not coming out of Fort Detrick. It was a shipment from Fort Eustice to Fort Detrick. According to this information here, he must be doing his work because he can cite by number the Federal regs as to the requirement—DMN 142.21.

There is no statement of disposal procedures, PUB-52-383-12, 383,12. There is no biological agent liable as specified by the postal system, PUB 52-383-11. I guess this gets us back into the question of enforcement and human error along the way.

Do you have any response that you can give us in writing as to evidently this noncompliance he experienced of materials going into your facility.

Colonel HUXSOLL. Mr. Chairman, I am not familiar with that, and additionally sometimes Fort Detrick, the name gets slammed around in various ways. There are multiple organizations at Fort Detrick, and my first question would be was it destined for USAMRIID?

Mr. McCLOSKEY. Addressed to USAMRIID, ATC, J.W. LeDuc, Disease Assessment Division, Fort Detrick, Maryland.

Colonel HUXSOLL. It was coming to our place, but I have no idea, you know, who was shipping that.

Mr. McCLOSKEY. Not being accusatory, but this is the type of thing that Fort Eustice had shipped to you.

Colonel HUXSOLL. Yes, sir. That could be a diagnostic specimen and that doesn't take away from the requirement, but the problem that we often face——

Mr. McCLOSKEY. I guess it had a small red label, biohazard, blood and fluid precautions.

Colonel HUXSOLL. I would have to look at that further. It could be diagnostic material coming in. We have capabilities there to perform the diagnosis, the laboratory diagnosis and so someone can be shipping that in there and it is very difficult to control what someone sends to you.

Mr. McCLOSKEY. I know, but that is what we are getting at today. This is not Joe Blow Labs. This is another military installation that you evidently do regular business with that had not complied with the regulations we are talking about today.

Colonel HUXSOLL. This is not one of our contractors that we regularly do business with.

Mr. McCLOSKEY. Maybe you can look at this and give us a report later. What about the obvious item raised in Mr. Miss's testimony? I am not saying this was any fault of anyone here, but at least until he got on the job and got communications going out to these various mailers and suppliers, as a matter of routine the canisters despite all the procedures and safeguards, which you so excellently described are popping open under various conditions in transit.

He says that has been cured substantially just because of the people he mailed to. Do you have any reaction to the fact that evidently there is occasional human error involved here?

Colonel HUXSOLL. Obviously, there is going to be human error once in a while, but the people we deal with I think are well aware of the requirements. I went back and looked at the people that—with whom we have contracts, where there is a deliverable, as part of the contract, and they are all coming in by commercial courier.

Mr. McCLOSKEY. Now, when I talked to Mr. Dashiell the other day, I believe—Colonel, you happened to be there—I guess some point was made of the fact, and I think one or the other of you hit on it today. Maybe Mr. Dashiell, that for whatever reason, lack of confidence or timing or scheduling or whatever, you don't use the U.S. mail on anything going out these days.

How long has that been the policy?

Colonel HUXSOLL. Since 1980 at least.

Mr. DASHIELL. Five-year period.

Colonel HUXSOLL. It goes back even further than that.

Mr. McCLOSKEY. Whatever, but it has been about five years now. But you do have materials obviously mailed to you in the U.S. mails of an etiologic nature.

Colonel HUXSOLL. Yes, sir.

Mr. McCLOSKEY. Which is obviously of some concern in the system as far as environmental and safety regulation.

Mr. Dashiell, have you had any contact with Senator Levin and his committee and the work he is doing over there.

Mr. DASHIELL. Some contact, yes, sir. In fact, he has a GAO survey also on-going and we have been working closely with them on that particular subject.

Mr. MCCLOSKEY. Okay. Now, you and the colonel did an excellent job the other day showing me the packaging and absorbent materials and just how difficult this would be to get out. I believe you said in this case all these organisms are not really going to live past that time of departure from the capsule if that were to happen accidentally.

Senator Levin and others, maybe Mr. Rifkin, would make the point, that these things are bred to be deadly and mainly we are not doing it in an offensive way, but we are doing it to be defensive. Correct?

He says flat no to the idea that these things are not going to multiply in the general environment. Are there some exceptions to this limited life span capability with all the items you deal with?

Mr. DASHIELL. Oh, yes, there are exceptions. There are exceptions to every rule, sir.

Mr. MCCLOSKEY. We are not talking about a rule here. We are talking about an organism that can break environmental restraints and possibly imperil people.

Mr. DASHIELL. Generally environmental influences and heat will render organisms sterile. Most bacteria would also be quite labile. Anthrax forms a spore which is very resistant to environmental influences and anthrax will remain in the environment for a matter of years.

However, that is more the exception that the rule.

Mr. MCCLOSKEY. But again you would say for the record that there are materials that could readily function or normally function beyond those canisters. Not everything is going to die with the first burst of air or sunlight.

Mr. DASHIELL. Not everything will die with the first burst of air or sunlight. It will take time.

Mr. MCCLOSKEY. And——

Mr. DASHIELL. The time will vary.

Mr. MCCLOSKEY. Can any of these organisms readily multiply?

Mr. DASHIELL. Well——

Mr. MCCLOSKEY. Much is made of whether the thing is a half an ounce vial or whether we are shipping around a gallon or something, and we have had testimony that something in a half ounce vial could wipe out the population of Minneapolis if you put it in a lake.

We are not talking about size here. We are talking about lethality.

Mr. DASHIELL. I might disagree with the fact that somebody says that a half ounce vial will wipe out a city. I do, in fact, disagree with that. That can be supported by the many tests that were performed when we had an offensive program.

A large amount of material properly disseminated would cause quote, what we consider a disaster. Most of these materials will not propagate in the environment unless they are in a suitable media. We grow these materials under very well defined conditions and, in

fact, viruses will generally not propagate outside of human cells and/or animal cells.

So, you do have to have a proper medium if you want them to propagate.

Mr. McCLOSKEY. Given some of the testimony we had today as the problems in the postal system regarding human error, evidently, the fact is that the CDC promulgates regulations but does not enforce them. Dr. McVicar, is there a need for a centralized enforcement mechanism, whether it be for these—whether it be your agency or another agency, for these regulations?

If you promulgate and don't enforce, what good is it?

Dr. McVICAR. By and large we find that the degree of compliance is extremely high. The people who are sending these types of materials through the mail are ordinarily doing it for a very good and right purpose.

They are submitting a diagnostic specimen from a patient, or they are trying to transfer materials between laboratories for some beneficial use. It is to the shipper's benefit to get the material to the receiver in good condition.

At CDC, for example, I asked some questions of the people in our receiving department. In 1987, for example, we received in excess of 35,000 packages—we do a lot of diagnostic work and most of these were diagnostic samples. Of those 35,000 packages, 66 were damaged. None of them leaked. We only knew they were damaged because when they opened the package they would find a vial with the stopper loose and the serum leaking out or something similar.

So in this particular system, this mini-survey that we ran, a failure rate of damage without leaking, there was zero leakage. There were actually only about two-tenths of 1 percent of the packages that were even damaged. I think this points out the desire of the shipper to get his sample through to the diagnostic laboratory intact and I think we would find that by and large this is the bulk of the biological material that is mailed.

Mr. McCLOSKEY. How would you feel about some consideration of a more definite enforcement office, perhaps within the CDC, for your regulations?

Dr. McVICAR. I think we would find it rather difficult. If I recall correctly, what Mr. Miss' citation mentioned were mostly Postal Service regulations that were violated. I didn't notice that there were any Public Health Service violations there. There are several agencies other than the Public Health Service who use this regulation as a basis for their own regulations. DOT has certain regulations. The Postal Service has certain regulations, and air carriers have other regulations.

There is a whole plethora of regulations governing packaging. I think it would be difficult from our standpoint. We get calls from literally all over the country. The calls that come about damaged packages we receive in our office. That red sticker has a phone number on it that says call the director of CDC. One of our people gets those calls, and they come in from all over the country, at all hours of the day and night.

I am having trouble envisioning a mechanism by which we could undertake enforcement. I am not a lawyer by any stretch of the imagination, but I don't know how that would be accomplished.

Mr. McCLOSKEY. I don't have any difficulty at all envisioning a mechanism. Things that difficult are attempted all the time. I quote from Mr. Biller, and I think your testimony implicitly alludes to it, "regulation by reference". All this regulation by reference creates the additional problem that no one is really in charge. Who polices compliance with DOT or Public Health Service regulations? The USPS, DOT, HHS. I won't go on. You and I have touched on this.

You say CDC has authority for governing interstate shipment of etiological agents, but has no enforcement program. That is one area that I am going to work on real hard by talking to Members of the committee, yourself, other experts, and Senator Levin. This is something I am very interested in.

Again, we have numerous questions for the record that we will get to you. Is there any other comment any of you would care to make or maybe an item of questioning or discussion we haven't gone into.

Dr. McVICAR. I would like to mention one thing to perhaps clear the record. Several times this afternoon a missing vial has been alluded to as being lost in the mail. The very extensive investigation looking into that situation led to the discovery that it wasn't in the package——

Mr. McCLOSKEY. You don't think it was sent?

Dr. McVICAR. It never got into the package. The package didn't fail. The package arrived in good condition. The vial was not in it. It was a breakdown of internal procedure that the vial itself wasn't packaged and sent.

Mr. McCLOSKEY. Obviously, you admit there was some uncertainty in the system that strained the system for a certain amount of time and resources?

Dr. McVICAR. Well, the uncertainty was laid to rest, we felt, after several weeks of very careful investigation that showed that it wasn't placed in other packages. The public health was preserved which is our business.

Mr. McCLOSKEY. I have one more question that I want to ask Mr. Dashiell and the Colonel. I don't want to go into all this in a laborious way, but could you, for my own comprehension, state again what we do and do not do in the area of biological resources that we are talking about today? Particularly there was something the Colonel said about not developing anything new, or it was my recollection that we develop all sorts of new things. Statedly defensive purposes, but there are some new things going on to my knowledge.

Colonel HUXSOLL. Yes, sir. We do develop new things, new vaccines and new drugs to protect folks. I might give you a couple of interesting examples and the way in which those have been used beyond protection of military people against some of these diseases.

Before I do that, I would like to point out also that a number of the organisms that are often times considered as potential biological warfare agents that could be used by an adversary against us are indeed natural disease threats.

It is important to develop protection, and if we should have to deploy U.S. forces worldwide to protect U.S. interests, we have got to send those folks there in a protected manner. I think it is very

important that that be recognized. So some of the work, and some of the work under the biological defense program addresses, for example, viral hemorrhagic fevers such as epidemic hemorrhagic fever or Korean hemorrhagic fever. We do have information on the military importance of these diseases in areas where some of those diseases are endemic.

I would like to point out that a new anti-virul drug recently tested in the Peoples Republic of China has been shown to be effective in treatment of epidemic hemorrhagic fever and in animal models is effective against Crimea Congo hemorrhagic fever. Of course, that program has led to other government agencies seeking our assistance in screening for new drugs against AIDS. We also developed a vaccine against Venezuelan equine encephalomyelitis. In the 1970's, that disease moved through Mexico into Texas. The vaccine that we developed was used in horses in Texas, the horses being the amplifying host. That vaccine quelled the spread of that disease. We also developed vaccines like Western equine encephalomyelitis and Eastern equine encephalomyelitis and we are the only folks in the United States that have that vaccine available. We provide that vaccine for numerous other people in the United States and elsewhere to protect high risk people working in labs and working in the field. By the way, we do a lot of that through the CDC.

It is interesting also that the Eastern equine encephalomyelitis vaccine was used to stop an outbreak of that disease in the remaining flock of whooping cranes, if you will, at the Patuxent Wildlife Research Station a couple years ago. So the products we develop get wide usage and those are the new things that we are developing. We are not developing a new virus or developing a new deadly bacterial agent.

Mention was made this afternoon of genetic engineering. Yes, we use genetic engineering and if we didn't, you ought to seek whatever it takes to have me relieved because I would not be spending the taxpayers' money in the most effective way. And so that is my answer on the questions of new things.

There is one more thing I would like to add. There was testimony this afternoon alluding to the fact that shipments are made just any old which way in laboratories, dumped into a box in the hallway and packed by individual investigators and that sort of thing. There may be some places where that occurs. I don't know. But in our facility we have a central packing facility, the individual who packs those shipments has been packing them for decades and everything that goes out of USAMRIID goes through him. So I can assure you there is one place where that is centralized and watched very, very closely.

Thank you, Mr. Chairman.

Mr. McCLOSKEY. Thank you, very much.

Mr. DASHIELL. I would comment only to amplify upon something Colonel Huxsoll brought up and I left a couple of papers with your staff. There was one that appeared last week, in fact, in Science Magazine on rubella fever which, I think, you will find very interesting.

I left a copy of the statement I made at the American Society for Microbiology which I think you will find interesting. That points

out that the type of program which we are developing in the biological defense area does not rely on individual vaccine and so forth. We are developing what we will call a generic and/or general approach to the problem.

One of the drugs that is being developed is the one that Colonel Huxsoll mentioned, a broad spectrum drug similar to penicillin which is effective against gram negative bacteria. This will protect against a group of viruses we are doing the same thing for detection because that is a critical issue. There is no way I can rapidly, accurately detect every new kind of thing. If we complete with what we are looking at as a generic detector using receptor sites, we will have then a general detector that says that is toxic, that is not toxic. It is not the kind of thing where we have to develop a new agent as was alluded to by some here this afternoon.

We are developing a generic or general defense mechanism. I don't have to develop new things to come up with that and we are not doing that.

Mr. McCLOSKEY. Thank you, very much for being here, Mr. Dashiell.

Thank you, gentlemen.

The Assistant Postmaster General Frank Heselton, Rates and Classification Department is next.

STATEMENT OF ASSISTANT POSTMASTER GENERAL FRANK R. HESELTON, RATES AND CLASSIFICATION DEPARTMENT, U.S. POSTAL SERVICE, ACCOMPANIED BY DONALD D. DILLMAN, DIRECTOR OF THE OFFICE OF CLASSIFICATION AND RATES ADMINISTRATION AND DARNLEY M. HOWARD, DIRECTOR OF THE OFFICE OF SAFETY AND HEALTH

Mr. HESELTON. I notice it has been a long afternoon in these hearings and while I have a relatively brief statement I certainly would be happy to summarize it for you if you would like.

Mr. McCLOSKEY. As you please, Mr. Heselton. I am under some time constraints, but not immediately pressing. Proceed as you prefer, and state your concerns.

Mr. HESELTON. As you indicated, I am Frank Heselton, Assistant Postmaster General, Rates and Classification Department. On my right with me is Donald Dillman, Director of the Office of Classification and Rates Administration and on my left Darnley M. Howard, the Director of our Office of Safety and Health. We are here at your invitation to discuss the mailing of hazardous materials and to review steps we have taken to minimize any danger these mailings pose to postal workers and to the public.

Our program is built from standards issued from the Departments of Transportation and Health and Human Services for the handling and transportation of hazardous materials outside the mails. We prohibit the same dangerous articles and require the same preparation and packaging. Postal employees are trained to help customers comply with these requirements.

We also provide assistance by cooperating with organizations in developing packaging guidelines for shipping hazardous materials. Although there have been no reported instances of any postal em-

ployees suffering significant injuries from handling these materials, we are aware of the potential danger.

We provide training on the handling of all hazardous material and guidance on dealing with accidental spills and leaks.

Mr. MCCLOSKEY. Can I interrupt for a question there? You were here for Mr. Miss. He said there was no previous training or procedures. I am not being hostile or accusatory. We can all do our jobs better. What was the breakdown there, the problem? Evidently he is doing scientific and environmental research and advocacy on the shop floor, so to speak.

Is that just an exception or are you intensifying this procedure now?

Mr. HESELTON. In the case of the Frederick situation, after he was involved in that spill in November, as he indicated, postal management felt something more had to be done in that facility.

Mr. MCCLOSKEY. Shouldn't there have been a little more foresight given? Evidently Frederick is a center for transportation of such items. Everything is coming in and out there.

Mr. HESELTON. That is an area that we want to pay attention to because it is a small office and it is, as you indicate, on a main transportation route for these materials. For that reason, yes, we would want to pay more attention to that kind of situation.

I think that is behind management's thinking there and, in fact, they are focusing on things that need to be done.

Mr. MCCLOSKEY. There wasn't much done before?

Mr. HESELTON. Before, we had generated a training program by which we make materials available to employees who are involved in the handling of mail, primarily the clerk and mail handler crafts.

Our recent history in that endeavor is in May of last year we revised the publication 52 that has been alluded to earlier that governs the acceptance of mail and issued 65,000 copies to the field to the people accepting mail there as part of the process to make sure that they are up to date in our procedures on acceptance.

Mr. MCCLOSKEY. I guess it is the same thing I am thinking of, the original clean up kit. Employees are given $100 and told to get a bucket and gloves and chlorox. I don't know how scientific that was at the time.

Mr. HESELTON. I think there is some science behind it. We have done two things since that incident and these are nation-wide. First, there was a memorandum sent to managers of the Safety and Health Service for Divisions indicating how they should handle biological or infectious materials, and in April of this year a Management Instruction was issued on hazardous leaks and spills indicting to the facilities that they should develop a standard operating procedure for handling spills.

The work done at the Frederick Post Office represents implementation of that management instruction.

At any rate, we are concerned that increases in etiologic agents in the mail will present a hazard to postal workers and to the public. They are required by law and regulation to bear an etiologic agent biomedical label. This proposed rule would not affect the mailability of biological products and diagnostic specimens when an Etiologic Agents/Biomedical Material label is not required.

Mr. McCLOSKEY. Mr. Heselton, are you getting any reaction to that proposed rule yet, as I alluded to previously that I find very dramatic. Are any of the labor or DOD people getting in touch with you, or is it too new to generate a response?

Mr. HESELTON. I expect it is too new. We have filed with the Federal Register people this notice; I understand it will be issued tomorrow. We asked that we receive comments back in 45 days. At this point, I wouldn't have expected to have received any comments. We will be anticipating them in the next 45-day period.

Mr. McCLOSKEY. Thank you. Mr. Heselton, is there going to be one systemwide health and environmental policy on this type of issue, or is each division going to have its own SOP?

Mr. HESELTON. We have one system-wide policy and we have one set of guidelines to the various Divisions on developing a standard operating procedure. They develop plans at each of the facilities in accordance with the guidelines that we indicate to them, so that they can tailor the guidelines to their specific facilities and to specific situations and types of mail they have there, but they are operating under one general set of guidelines which indicates to them the kinds of things they should look at, safety materials they should have on hand and protections they should avail themselves of.

Mr. McCLOSKEY. I know you are going to say yes, but obviously it would be common sense to make some sort of final scientific and administrative headquarters review and coordination so that one poor division isn't missing a very basic safety item or something that someone else thought better in another division.

You believe in decentralization, but to some degree, national uniformity, I think, with similar substance is going to very important here.

Mr. HESELTON. Yes. We agree. To that end, in fact, we have safety people from Headquarters going out to the various facilities and, in fact, looking at the plan that they have established, and reviewing it for adequacy and for consistency with the overall guidelines.

That basically completes my prepared remarks, Mr. Chairman. I would be happy to answer any further questions that you have.

[The statement of Frank R. Heselton follows. Also included are responses to written questions.]

STATEMENT OF FRANK R. HESELTON
ASSISTANT POSTMASTER GENERAL
RATES AND CLASSIFICATION DEPARTMENT
BEFORE THE SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION
HOUSE COMMITTEE ON POST OFFICE AND CIVIL SERVICE

June 23, 1988

Mr. Chairman:

I am Frank R. Heselton, Assistant Postmaster General, Rates and Classification Department. I am accompanied by Donald D. Dillman, Director of the Office of Classification and Rates Administration, and Darnley M. Howard, the Director of our Office of Safety and Health. We are here today at your invitation to discuss the mailing of hazardous materials and to review the steps we have taken to minimize any danger these mailings might pose to postal workers and the public.

The statutory framework concerning the mailability of hazardous substances is set forth in 18 U.S.C. 1716. The first subsection of that provision generally prohibits the mailing of certain "injurious articles," including "all disease germs or scabs, and all other natural or artificial articles, compositions, or material which may kill or injure another, or injure the mails or other property." The next subsection of this provision authorizes the Postal Service to permit such items to be mailed, in accordance with prescribed preparation and packing requirements, if they "are not outwardly or of their own force dangerous or injurious to life, health, or property."

In implementing this provision, the Postal Service has authorized the mailing of articles which may contain infectious agents only if they are prepared in accordance with the strict

packaging standards issued by the Departments of Transportation and of Health and Human Services. To be accepted for mailing, the article must be placed in waterproof inner containers which are not permeable by the contents. When an item is "other than dry," the inner containers must be packaged in cushioning capable of completely absorbing the contents in the event the inner containers leak. The cushioning and inner containers must then be enclosed in a sealed, nonpermeable outer receptacle, which may be used as the shipping container. The contents must also be identified, and the address of the mailer, as well as that of the addressee, must be placed on the exterior of the package. If the article mailed is an etiologic agent -- a viable microorganism or its toxin which causes, or may cause, human disease -- the outer container must display a warning label.

Postal employees are trained to help our customers comply with these requirements. Acceptance clerks are available to advise mailers of particular preparation and packaging needs, and to explain why improperly packaged substances may not be mailed. The Postal Service also complies with requests from medical research institutes and packaging manufacturers for assistance in evaluating their containers, packaging materials, and preparation methods. We provide assistance in other ways as well. For example, we cooperated with the National Committee for Clinical Laboratory Standards in its efforts to develop a set of packaging guidelines for shipping infectious substances.

To ensure that potentially sensitive shipments are properly processed once deposited in the mail, we provide regular training courses on the handling of all hazardous materials, including etiologic agents. This training includes guidance in effectively dealing with accidental spills or leaks of hazardous substances. There have been no reported instances of any postal employees suffering injuries from handling these materials.

The general intent of our current regulations is to authorize the mailing of disease germs, diagnostic specimens, and biological products if they are properly packaged. We have recently learned, however, that some customers propose increased use of the mails to transmit etiologic agents. Since the mailings of etiologic agents in such numbers might present a hazard to postal workers and to the public, we have concluded that the transmission in the mails of all such items should be prohibited.

Accordingly, the Postal Service is preparing to seek public comments on a change in regulations to prohibit the mailing of any material which is required to bear an Etiologic Agents/Biomedical Material label under regulations issued by the Departments of Transportation and of Health and Human Services. This proposed rule would not affect the mailability of biological products and diagnostic specimens when an Etiologic Agents/Biomedical Material label is not required. These products would continue to be mailable under our proposal, provided they are properly prepared and packaged under the applicable stringent regulatory packaging requirements.

ASSISTANT POSTMASTER GENERAL
Government Relations Department
Washington, DC 20260-3500

August 25, 1988

Honorable Frank McCloskey
Chairman, Subcommittee on Postal
Personnel and Modernization
Committee on Post Office
and Civil Service
House of Representatives
Washington, D.C. 20515-6250

Dear Congressman McCloskey:

This is in response to your August 1 letter to Frank Hesselton, Assistant Postmaster General, Rates and Classification Department, posing additional questions for the record of the June 23 hearing on the transportation of toxic substances through the mail.

Enclosed you will find the responses to your questions. If you require any additional information, please contact me on 268-3731.

Sincerely,

William T. Johnstone

Enclosure

Questions from Chairman Frank McCloskey for the record on the mailing of etiologic agents for the U.S. Postal Service.

1. How often are your training courses on the handling of etiologic agents offered? To whom are these courses offered? What fraction of postal employees handling this material have received this training?

   Answer: There is no set schedule for training involving hazardous materials such as etiologic or biological materials. Postal policy is that all employees involved in the acceptance and handling of such materials will receive initial and refresher training, using postal developed and "off-the-shelf" training from commercial or government sources.

   There is specific training related to the job, as well as a requirement for "awareness" training for all employees. Specific postal training currently in use targets acceptance personnel, mailhandlers, transfer clerks, carriers, and supervisors. Training for spill and lead response personnel has been done through locally developed instruction which may also involve local fire departments. Training will be supplemented by a postal developed spill and leak response course which is expected to be implemented during 1989. Awareness materials designed to keep the postal work force attuned in general to acceptance and handling of hazardous materials, and more recently etiologic agents and specimens, is made available to a majority of the workforce. This is accomplished through safety talks, use of Handbook EL-812, Hazardous Materials, and memorandums, bulletins, and posters issued from headquarters.

   Thus far, during fiscal year 1988, participation in Postal Course 21511-00, Hazardous Materials, has totaled 12,299 with 18,744 training hours used. This course has also been used in prior years to train postal employees.

2. According to the American Postal Workers Union each of the 72 divisions issues its own standard operating procedures for hazardous material spills and leaks. Why is there no centralized control or review of these SOPs?

   Answer: In 1982 a Management Instruction was issued to the field which mandated SOPs, based on a fixed set of criteria. The field was given latitude to tailor the SOP to the locality. That instruction was revised in April of this year. It still has specific requirements for administration, procedures, equipment, facilities and

training but allows division managers the flexibility they need. These SOPs are reviewed as part of mandatory safety and health evaluations.

3. Why was no follow up medical surveillance done on the 129 postal workers who were hospitalized in July, 1986?

Answer: The incident that occurred in Eugene, Oregon, in July of 1986 did not involve wholesale hospitalization of postal employees. One employee was observed for six hours and released. The remaining employees with either potential exposure or symptoms associated with the chemical spill were examined and released. Selective follow ups, including liver function tests, were conducted as appropriate. Follow up examinations were not required because employees showed no signs of adverse effects from the incident (through examination and blood tests). Additionally, the nature of the exposure, which was transient and relatively low level, would not be expected to result in any chronic health effects.

4. What items are provided by the Postal Service to postal workers to handle a leaking package which contains an etiologic agent?

Answer: It is Postal Service policy that mailhandlers and other employees who routinely handle biological specimens and etiologic agents be supplied with latex gloves and aprons. Gloves are also to be available to other employees in the event such a package is encountered. Employees designated to handle spills and leaks are to receive special training, and wear impermeable, heavier gloves to protect against broken glass, apron, boots, chemical splash face shield and goggles.

5. Your statement indicates, "...we have concluded that the transmission in the mails of all such items (etiologic agents) should be prohibited." How many packages a year do you estimate this would cover?

Answer: We have no way of making a realistic estimate, as we do not compile information of this type. However, it has been estimated by a laboratory commenting on a recent Federal Register notice on the prohibition of etiologic agents in the mail that "at least 100,000 shipments of etiologic agents are made by mail."

6. Who do you feel should have regulatory enforcement of the regulations issued by CDC and the Department of Transportation regarding the transportation of etiologic agents?

Answer: Enforcement of the regulations involves ensuring that only properly packaged and labeled materials are transported. We must rely on the technical expertise of Center for Disease Control (CDC) to determine what can be transported safely. Perhaps a requirement to show the container's contents and the quantity would be helpful in enforcing the regulations as long as the sender properly labels the outer container. Regulatory enforcement of postal regulations should remain with the Postal Service and the transporter of the material. Complete enforcement of regulations requires the cooperation of the sender regarding labeling and packaging, and the ability of the transporter to inspect packages and to analyze the materials being transported. The Public Health Service (CDC) and the Department of Transportation should regulate what materials and quantities can be transported safely. Postal regulations can be amended to incorporate the provisions of the Public Health Service (CDC) and Department of Transportation regulations.

7. How do you presently ensure that customers who send etiologic agents through the mail stream adhere to the CDC guidelines and postage regulations for packaging?

Answer: Items which are mailed as First-Class Mail, Priority Mail and Express Mail are sealed against inspection. In general, no person may open, read, search, or divulge the contents of mail sealed against inspection. Therefore, compliance with regulations is the mailer's responsibility. If there are leaks, the sender is contacted to ensure that the requirements are understood. In addition, the Postal Service has examined manufacturers' containers to help ensure they meet applicable requirements. As stated for Question 6, proper labelling would be helpful.

8. Do you have any legislative recommendations for Congress regarding this issue?

Answer: In addition to the present Law, Title 18, USC 1716, a requirement to show the container's content and quantity might be helpful. Also, a requirement to have CDC license laboratories, organizations and other mailers who are involved in assessing the capabilities of laboratories might be helpful.

Mr. McCLOSKEY. I think we will have further questions for the record. I would say I have served for a couple of years as chairman of one of the two major subcommittees on the Post Office and Civil Service Committee involving the post office. One of my biggest disappointments is lack of system-wide standards and enforcement, not only in this area but in the areas of environmental safety generally.

I think there is just so much more to do in this area. How do you feel about the DOD's implications that private express service is better than the post office for their time schedules?

Mr. HESELTON. My understanding is that their use of the private carriers in that regard was because, at that time, the private carriers offered tracing of what they were carrying at each stage of handling and we could not offer that.

At this point our express mail does offer that capability.

Mr. McCLOSKEY. Now, can you state any numbers as to defects in biohazardous and etiological materials getting disrupted in the postal system. At how many locations and are some locations more common than others?

Mr. HESELTON. We have a tracking system. When we have a spill of hazardous materials or breaking open of a package of hazardous materials in which there is contact with an employee or serious disruption to operations or damage to equipment, there is a form completed, a report made on that particular incident.

On the basis of the forms submitted, we are looking at out of a total mail stream of some 160 billion pieces, approximately some 200 reported instances per year of that kind of thing.

Of those reported instances, perhaps one-quarter to one-third will turn out to be an etiological or biological agent of some kind.

Mr. McCLOSKEY. Maybe 50 to 75?

Mr. HESELTON. Perhaps a little fewer than that, I think. Less than that. The figure for last year that sticks in my mind is 38 for that, for 1987.

Mr. McCLOSKEY. You are aware at this time of no one being significantly injured or developing any illness or anything like that.

Mr. HESELTON. That is correct. We are developing our program not because we have had some specific instances of injury, but because we are acutely aware of the potential danger we might face. That is our primary concern.

Mr. McCLOSKEY. Well, I thank you very much. I would really appreciate being apprised of your final situation with the division as to those regulations and national input. I do think you are going to get some reaction in the scientific and the defense communities when the proposed regulation is advertised tomorrow that such etiological materials will not be in the mails.

I commend you for your innovation, and we will see what the final result of that is. I thank you gentlemen for being so patient. It has been a moderately long afternoon. This hearing stands adjourned.

[Whereupon, at 4:30 p.m., the subcommittee was adjourned.]

[The following statements were received for the record:]

90-365 O - 88 - 5

The recent history of the Public Health Service's involvement in the interstate shipment of etiologic agents, diagnostic specimens, and biological products and the present regulatory requirements are summarized in the enclosed reprint of: Richardson, John H. Transportation of clinical specimens and etiologic agents. 1981.*/ In: Balows, A. and Hausler, W. eds. Diagnostic Procedures for Bacterial, Mycotic and Parasitic Infections. American Public Health Association. Washington, D. C. 57-66.

The domestic and international transport of etiologic agents, diagnostic specimens, and biological products by postal and private sector carriers is a common place event. The transport of such materials is often essential in providing diagnostic services and conducting research vital to individual and national health interests. In the 29 years that the Public Health Service (i.e., FDA, CDC) has regulated the interstate shipment of known or potentially infectious materials, there has not been a single case of infectious disease documented in postal service or other transportation personnel who handle literally thousands of shipments of such materials on a regular basis.

The containment packaging specified for etiologic agents in 49CFR, Part 72 is a major factor in minimizing the likelihood of damage or leakage of infectious materials in transit. Additionally, since 1972, the Interstate Quarantine regulation has provided a 24 hour - 7 day a week

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*/ Not printed. Retained in hearing file.

"hot-line" for reporting any evidence of damage or leakage of identified shipments of etiologic agents during any stage of transport. Many such incidents have been reported, but prompt response and corrective actions have prevented any infections.

In light of current deliberations, it is pertinent to assess the specific infection risks of the etiologic agent of anthrax - Bacillus anthracis. This microorganism is a large gram positive spore forming bacterium which may survive in soils for long periods of time. Anthrax is a classical zoonoses - a naturally occurring infectious disease of animals which may be transmitted to humans. While epidemics have presumably occurred in historical times, the disease is a rare, sporadic, and typically occupationally-associated infection in the United States and other developed countries.

The most typical clinical form of anthrax is a skin lesion or carbuncle. Infections may, on rare occasions, involve the lungs or intestinal tract. Infections respond to treatment with penicillin or other broad spectrum antibiotics. A vaccine is available and is used in personnel with a demonstrated high occupational risk of infection.

The infective dose of B. anthracis - the number of viable organisms required to infect 25 - 50% of persons exposed via the respiratory tract is on the order of 1,300 organisms. In the laboratory setting,

anthrax is a moderate risk agent (i.e., Biosafety level 2) and work with diagnostic and laboratory scale quantities are safely conducted on the open bench using good laboratory practices.

In contrast, a number of high risk microorganisms are regularly handled in state health department, clinical, and hospital laboratories and are regularly transported by mail or private carriers. For example, there are in excess of 20,000 cases of tuberculosis diagnosed in the United States annually. Diagnostic specimens and cultures are regularly transported by mail for typing, antibiotic sensitivity testing, and other laboratory studies. Tuberculosis is a very infectious organism and has been a significant cause of occupational infections in laboratory and health care personnel for the past 100 years. Ten or fewer organisms typically constitute an infective dose for healthy human adults. The potential for aerosol transmission exceeds that of any other infectious agent, including anthrax, regularly transported or handled in clinical and diagnostic laboratories in this country.

The recent history of transporting infectious materials by civilian and military facilities documents that the risks of human or environmental contamination is extremely low. As with other human endeavors, however, these risks are never zero. Hopefully, this and other testimony will add balance to your discussions in realistically assessing the risks versus the benefits of transporting biomedical materials for legitimate purposes.

Finally, much of the background information included in Mr. Van De Kamp's letter is subjective, technically incorrect, and misleading. For example, Q fever (a rickittsical organism - not a virus) is epizootic in sheep flocks in most western states including California. At the time of lambing, billions of viable and infectious rickettsia are shed in the birth fluids and placentas of infected sheep. Collectively, this incredible load of microorganisms, produced and shed under natural conditions, far exceeds the production capability of any laboratory in the world for which I have personal knowledge.

John H. Richardson

John H. Richardson, D.V.M., M.P.H.
President, American Biological Safety Association

June 23, 1988

Statement of Dr. Robert E. Shope submitted to the Subcommittees on Postal Personnel and Modernization, and Research and Development of the U.S. House of Representatives:

Mr. Chairman and Members of the Subcommittees:

I am Robert E. Shope, Professor of Epidemiology at the Yale University School of Medicine and Director of the Yale Arbovirus Research Unit. This Unit has served since 1965 as the World Health Organization Centre for Arbovirus Research and Reference. We maintain a collection of over 500 serotypes of arthropod-borne viruses -- that is viruses transmitted by mosquitoes, ticks and other biting arthropods. These viruses are etiologic agents. They infect billions of people in underdeveloped areas of the world and their public health impact is enormous.

Our organization performs an essential service to laboratories and research scientists throughout the United States and the rest of the world by providing these viruses to qualified research organizations on request. We regularly supply the American Type Culture Collection, our national repository. We are relied upon by the Centers for Disease Control, Division of Vector-Borne Virus Diseases in Fort Collins, Colorado for viruses which they need in order to diagnose illnesses contracted by U.S. citizens abroad and epidemics of possible exotic diseases in the U.S. We work closely with the U.S. Department of Agriculture. In January of 1987 a viral disease in sheep left large numbers of aborted and deformed lambs in a zone extending from Texas to Nebraska. We were able to ship a virus from our collection which was used in Texas and at the Animal and Plant Health Inspection Service Laboratory in Ames, Iowa for diagnosis and research of these cases.

We preserve the viruses by drying them and we normally ship them at ambient temperature by the U.S. Postal Service. The etiological agents are packaged, labeled, and shipped according to federal public health regulations (42 C.F.R. Part 72). In our experience, the Postal Service has been fully reliable. We request acknowledgment of receipt from the recipient. Since 1965, we have not lost shipments or suffered damaged packages.

We believe that in approaching the question of safe means of transporting these materials, it is important that proper risk assessment be carried out, and that it be done by experienced persons trained in the scientific method. Human error has been involved in the recent accounts in the press of mislabeled vials and leakage from packages shipped from other locations. Human error can be minimized by education and by enforcement of the current regulations. Though its consequences can be mitigated, human error will not be prevented by changes in the regulations. We believe from extensive experience with thousands of shipments since 1965 that the present regulations governing interstate transport of etiologic agents are sound and have served their purpose well. We believe that should more stringent regulation be contemplated, care should be taken not to burden world public health research except as necessary to achieve a commensurate contribution to public safety.

I thank the subcommittees for receiving this statement. My message in summary is that the present system of regulation on the shipment of etiological agents works well; I urge that Congress not change it without first carrying out proper risk assessment. By changing it you could deprive the U.S. health and research establishment of critical services.

MAILING OF BIOLOGICAL TOXINS

WEDNESDAY, OCTOBER 5, 1988

HOUSE OF REPRESENTATIVES,
COMMITTEE ON POST OFFICE AND CIVIL SERVICE,
SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION,
Washington, DC.

The subcommittee met, pursuant to call, at 10:05 a.m., in room 311, Cannon House Office Building, Hon. Frank McCloskey (chairman of the subcommittee) presiding.

Mr. MCCLOSKEY. Good morning. The Subcommittee on Postal Personnel and Modernization of the Post Office and Civil Service Committee hearing is now in session. I am Chairman Frank McCloskey.

In June, this subcommittee conducted a joint hearing with the Subcommittee on Research and Development of the Armed Services Committee on the transportation of etiologic agents through the U.S. mail. At that time, the subcommittee discovered that there was no agency responsible for enforcing the rigorous packaging requirements developed by the Centers for Disease Control.

There are stringent packaging requirements for the shipment of etiologic agents. However, there is no guarantee that these packaging procedures are being followed. In fact, there are reports of improperly packaged biological materials leaking to such a degree that the outer surface of the package becomes wet, and worse than that.

After the hearing, the Postal Service published a proposed regulation to ban all mailings of etiologic agents as a result of the concerns that were raised at the hearing. Subsequently, I contacted research institutions around the Nation, including the National Institutes of Health, to discuss the possible effects of this ban on scientific research.

I am greatly concerned that banning the mailing of these biological agents would have a detrimental effect on standard medical research and diagnostic procedures. I believe that full enforcement of existing regulations should guarantee public safety without jeopardizing scientific research. Amending the Clinical Laboratory Improvement Act to require that labs be certified in the CDC packaging requirements for transportation of etiologic substances is also a possible way to ensure the health and welfare of postal workers and the public.

In today's hearing, we hope to examine the implementation of the CDC regulations. We have Dr. McVicar of the Centers for Disease Control here. The potential danger that these materials present to postal workers and to the general public clearly man-

dates that all possible precautions be taken in the mailing of these materials. I am confident that cooperation between Congress and all the regulatory agencies will lead to a substantial reduction of the potential risks involved.

With that, we will proceed to our first witness, Assistant Postmaster General Frank R. Heselton, Rates and Classification Department, U.S. Postal Service.

Good morning, Mr. Heselton. I am really glad to have you here, and I understand the Postal Service is making real progress on this problem. I will let you proceed as you like, and we will accept your formal statement for the record.

STATEMENT OF FRANK R. HESELTON, ASSISTANT POSTMASTER GENERAL, RATES AND CLASSIFICATION DEPARTMENT, U.S. POSTAL SERVICE

Mr. HESELTON. Thank you, Mr. Chairman.

I am Frank R. Heselton, Assistant Postmaster General, Rates and Classification Department. I am here at your invitation to discuss our customers' concerns and to discuss related matters on the Postal Service's proposal to ban etiologic agents from the mail.

The present regulations on the mailing of disease germs and biological products contained in section 124.38 of the Domestic Mail Manual have been in place for approximately 15 years. They implement the provisions of Title XVIII, United States Code, section 1716, regarding the acceptance of disease germs in the mail.

Postal Service regulations follow the Centers for Disease Control rules in CFR 42, section 72, and Department of Transportation rules in CFR 49, section 173.386 and 173.387. In essence, to move in the mails, such material as etiologic agents, diagnostic specimens, and biological products which may cause disease must conform to applicable Federal packaging and labeling regulations.

As a result of an environmental impact statement by the Department of the Army regarding its intent to use mails for transportation of etiologic agent material to and from Dugway, Utah, Defense Biological Laboratory, concerns were raised for the safety of the public as well as for postal employees.

Because of the increased potential for mailings of this type, as well as for certain diagnostic specimens, which may contain such viruses as Hepatitis B or those related to AIDS, action was considered necessary to eliminate a potential health hazard from the mails.

The Postal Service, therefore, proposed in the Federal Register on June 24, 1988, to prohibit the mailing of etiologic agents, or material reasonably believed to contain them, which are required to bear an Etiolgic Agents/Biomedical Material label under Department of Transportation and Department of Health and Human Services rules.

Proposed rules are published in the Federal Register to give all concerned parties an opportunity to comment regarding their impact. The comments and concerns of interested parties are thoroughly evaluated. At the conclusion of this evaluation process, a decision is made to publish a final rule, or withdraw the proposed rule, or publish another proposed rule. There is no specific time

frame in which this decision must be made so that a thorough evaluation, including the use of additional expertise, can be accomplished.

The original comment period was for 45 days ending on August 8, 1988. It was extended to August 22 at the request of a medical association to allow time for its thorough consideration.

Five hundred and eight comments were received during the comment period. Seven responses favored the ban. The balance of the comments were from doctors, including allergists, pathologists, and biologists, from hospitals, laboratories, colleges and universities, including departments of biology, pathology, medicine, from medical centers, and from associations of pathologists and biologists, State and Federal health associations, as well as one postal employee, and from individuals. These responses opposed the ban for one or more of the following reasons:

One: The ban would have a negative impact on diagnostic, research, and laboratory certification capabilities or proficiency testing.

Two: There has been no prior record of anyone being accidentally infected in the handling of at least 100,000 shipments per year in the mails for over 25 years. One commenter stated that the period of time was 50 years.

Three: Increased transportation costs when shipping with other carriers as well as potential lack of readily available transportation by other means could reduce or eliminate effective response time for diagnostic purposes and adversely affect medical research and education.

Four: A ban could lead some postal customers to improperly identify and package materials and mail them anyway.

The Postal Service wishes to avoid the risk of substantial injury from potentially hazardous materials to postal employees and to the public through appropriate acceptance and handling procedures.

The Service does not wish to have a negative impact on medical diagnosis or medical research and laboratory certification capabilities. It does not want to increase medical costs or have such onerous rules that mailers would ignore packaging and labeling requirements and mail the potentially hazardous materials anyway.

We must, however, consider the potential risk to the public and to our employees in handling and delivering this material along with all other mail. We must either eliminate the risk, if possible, by refusing to accept this material or minimize the risk to a point which is acceptable when considering all the public health concerns. It may be possible to reduce the risk by reducing the quantity permitted for medical purposes per parcel or requiring better packaging and more expeditious means of movement in the mail. We do not plan to go ahead with our rule-making until these issues can be more fully explored.

The Postal Service does not have expertise of its own in the areas of biological materials or etiologic agents. Since the primary expertise in matters dealing with etiologic agents and the transportation of this type of material is in the Centers for Disease Control and the Department of Transportation, we have enlisted their as-

sistance in these technical areas. Issues we are addressing include the following:

One: What is an etiologic agent?

Two: Are there levels of hazard among etiologic agents?

Three: How can "material reasonably expected to contain an etiologic agent" be defined?

Four: What other procedures may be required regarding supposedly noninfectious diagnostic specimens? and,

Five: Can potentially hazardous material be more securely packaged for safer handling?

Based on their expertise, we have contacted CDC and DOT for assistance in developing universal standards in this area. Although the Postal Service monitors the appropriate rules of other regulatory agencies, such as CDC and DOT, it does not have the in-depth knowledge or staffing to develop technical standards on etiologic agents such as those contained in CFR 42.

Therefore, the Postal Service needs the assistance of these agencies. The Postal Service can, in turn, provide those agencies information on any hazardous materials discovered in its system through packaging failures.

Any mailability rules and preparation requirements must take into account the way mail is accepted, handled, and processed. Except for tagging of mail sacks containing hazardous material or when tendered to an airline, mail pieces containing hazardous materials are not handled separately from other mail. Mail is processed together in batches manually and on automated equipment so that pieces containing hazardous materials receive no treatment different from that accorded the other categories of mail. As a result, parcels of hazardous materials are merged into the mail stream and tend to be invisible within it even though the Etiologic Agents/Biomedical Material label is attached.

Mail handling takes place in thousands of sites, many of them too small to be prepared for any other than basic identification, handling, and leakage containment procedures for hazardous materials. There is a need, therefore, to exclude materials from the mail stream that become deadly or very dangerous in the event of a package failure and to restrict the quantities of hazardous materials shipped in accordance with rules established by CDC and DOT and by postal experience.

Regarding enforcement of regulations, if the contents of an article presented for mailing, as described by the mailer or otherwise, are determined to be nonmailable, the article is refused. An article also may be refused if the customer fails to demonstrate that potentially hazardous material is properly packaged. The Postal Service also can report hazardous materials packaging failures and related information when packages break open or fail in mail processing through our hazardous materials incident reporting system.

However, the Postal Service is unable to screen all parcels to determine what hazardous materials are being mailed and whether they are properly identified and packaged according to regulations because of legal and practical constraints. Under existing law, a search warrant is required to open first class mail, the class at which most hazardous material would be mailed.

As a practical matter, packages containing hazardous materials are too small a portion of the mail stream to be detected by random screening procedures. Hazardous materials may account for anywhere from one in 100,000 to one in 1,000,000 pieces anywhere in the mail stream. Sampling of the mail stream, therefore, would not yield sufficient observations of packages containing hazardous materials to be informative.

Mr. Chairman, this completes the Postal Service's outline of customer concerns and other matters related to the handling of etiologic materials in the mail. We would be pleased to respond to your questions.

Mr. McCLOSKEY. Thank you very much, Mr. Heselton.

In interpreting the gist of your statement, you would say that improvements in procedures and enforcement, detection, and so forth are under way and that you are consulting with the CDC and other Governmental agencies. You also state that the Postal Service is not really equipped to be a scientific expert on such technical, if dangerous and pressing, matters. Would you say that is a fair interpretation of your testimony here?

Mr. HESELTON. Yes, Mr. Chairman, that is a fair summary of my testimony.

Mr. McCLOSKEY. I believe you were at our first hearing when Mr. Miss, from the postal facility where there was a leak in a package, appeared. He, at the time, had not received any training as to hazards from etiologic substances. Indeed, there was a very interesting and colorful story of being delegated as the immediate, responsible person to become expert, to go out and buy the buckets, get the mop, being issued a pair of rubber gloves, and being told to develop the safety program. So we are in a time of transition now.

Is there anything being done, as far as education and enforcement generally, in this transitional period and particularly at facilities where we are going to see a regular, definite volume of these etiologic agents?

Mr. HESELTON. Yes, Mr. Chairman. With regard to the Frederick, Maryland, situation, which is the post office, as you will recall, where Mr. Miss was stationed, I have personally visited that post office and assured myself that that post office does have the required safety materials there for handling of a hazardous spill. That post office also has supplies of a hazardous materials handbook that the Postal Service printed in 1987 in quantity of some 300,000 copies, a copy of which is provided to incoming postal employees, new employees, who are going to be handling mail.

Mr. McCLOSKEY. Is that generai distribution for all mail handlers?

Mr. HESELTON. This is for general distribution. We have assured ourselves that there are supplies of this particular handbook at the Frederick post office itself, and they are there.

In addition, in sites in which we can anticipate the handling of some hazardous material, the primary way that we have conveyed information on the safety requirements is through a series of safety meetings which are held, conducted by a supervisor on guidance from headquarters with the employees under his supervision, and we have undertaken to do that in facilities which have occasion to handle these materials.

Mr. McCLOSKEY. Also, I believe your statement today indicates the definite possibility that you anticipate there will be some substances deemed nonmailable or that you really don't want to handle everything considered, given all the risks and problems. Could you elaborate on that a little bit?

Mr. HESELTON. We are certainly considering that possibility, and the substances that we are looking at specifically are those that, if they did escape from the packaging that they are in in mail handling, that they would be so dangerous to an employee that there would be no way to recover from any infection or any damage that might be caused. We certainly would focus on those particular materials.

I would hope that that kind of material gets mailed relatively infrequently in the mail stream so that we would not adversely affect the health care industry or other industries that would rely on the shipment of such substances, but we would be looking at that.

Mr. McCLOSKEY. One of the things that comes to mind again, as we all know, is our defensive chemical and germ warfare program. I just wonder how far you are into obtaining technical briefings and information as to when a decision is going to have to be made on certain dangerous substances. Even the DOD here did say, not enthusiastically, but when pressed, that yes, they are dealing with dangerous things that could live outside the immediate prepackaged or packaged environment—previously packaged environment, I guess.

Mr. HESELTON. Mr. Chairman, the look that we have had so far at those substances suggests that they tend to be mailed outside of the postal mail stream primarily using a carrier who can supply traceability and tracking for the mailing of that kind of substance, because the mailer generally wants to know where in the country that substance is when it is in transit.

As I indicated in my prior testimony, express mail is potentially a source of that kind of tracking ability, but that is just being put in place at this point.

So, in summary, our experience is that mailers of this type of truly dangerous material tend to look for some alternative to the mail and mailing, and we do not believe that we are carrying very much, if any, of that kind of material at this time.

Mr. McCLOSKEY. You don't think you are carrying very much, if any. Okay.

How about structural concerns at some of your larger bulk processing centers? I have heard commentary from the postal community as to the overall environment and the work place being conducive to smashing of packages and so forth. Is there any special emphasis right now on these problem areas?

Mr. HESELTON. I am not familiar with emphasis in the last year. Earlier in this decade when we were still experiencing problems in the bulk mail centers, we did look at ways of reducing package damage. At this point, from the information that I have, I don't think that we have a problem that is anywhere near the magnitude that we might have had in the seventies and early eighties when these centers were still shaking out of the kind of mail stream that they were being asked to handle.

I am not aware that this, at this point, is a significant or a serious problem.

Mr. McCLOSKEY. Are you working with the CDC and the NIH and the DOD to focus on the actual post offices right now where such packages are likely to be, in concentration?

Mr. HESELTON. I am not aware that we have had discussions with them at this point at to the actual post offices involved. I think our discussions at this point have been along the lines of the five areas that I outlined in my testimony. We may get to the point in discussions with them when we talk about the specific procedures that are used at facilities which tend to handle these materials.

Mr. McCLOSKEY. Could I suggest that might be a promising avenue of inquiry.

What occurs after a damaged package is reported to CDC? Does the Postal Service or the CDC have the authority to destroy or otherwise remove from the mail a damaged mailing, or do constitutional protections of mailings hamper or impede such action?

Mr. HESELTON. Yes, the Postal Service does have authority to remove from the mail an item that is hazardous, that is illegally in the mail, should not have been mailed, or that is obviously not properly packaged. In fact, that is the procedure that we follow.

At the same time that the hazardous substance report is prepared, we will get in touch with the customer who mailed that package and indicate to them the violations involved, and we will follow up with our own staff in terms of potential damage that might be a result from the package breaking open in the mail stream.

Mr. McCLOSKEY. Do you have any present figures on how often bio-hazardous materials are reported in packaging failures?

Mr. HESELTON. Right off-hand—and I am looking at incidents of reporting of several hundred packages of hazardous materials breaking open each year—my understanding is that agents that could be considered etiologic agents, medical samples, or biological agents generally constitute, in an average year, some 30 to 50 packages of that type.

Mr. McCLOSKEY. Thirty to fifty?

Mr. HESELTON. Thirty to fifty.

Mr. McCLOSKEY. In some written follow-up to previous questions I submitted to you, I asked as to legislative recommendations. The Postal Service's response was that, in addition to present laws under Title 18, USC, a requirement to show the container's content and quantity might be helpful. Also, a requirement to have CDC license laboratories, organizations, and other mailers who are involved in assessing the capabilities of laboratories might be helpful. Would you still recommend that?

Mr. HESELTON. We are still looking at that as possible alternatives, particularly, I think, with emphasis on limitation of quantities in the mail to quantities that would be less likely to leak out of the container should some packaging failure occur. We have suggested that the licensing of particularly the larger mailers of these materials be looked at, but we haven't done any further exploration of that alternative.

Mr. McCLOSKEY. Have you considered sending all etiologically problematic packages by registered mail? Would that be a viable solution as far as getting that out of the bulk mainstream?

Mr. HESELTON. My understanding is, from talking to some mailers of these materials, that time is often of the essence in transit for these packages, and one of the problems that would be encountered with putting these kinds of materials into the registry stream is that registered mail, because it is signed into and out of each postal operation, tends to move a little more slowly than it would if it were not registry. So it comes down to a question as to whether, if we put these materials in that mail stream, whether we could provide the appropriate transit time that the mailer is anticipating.

Mr. McCLOSKEY. I would assume that time may or may not be of the essence in any particular case with various substances. Wouldn't you say that is something to look at?

Mr. HESELTON. It is something to look at, and, in fact, now we do require certain substances to move in the registry mail stream.

Mr. McCLOSKEY. I may have some other written questions for you, Mr. Heselton, I just want to thank you today for appearing and for all your good work in this area. I think there is a lot more work to do though, and, quite frankly, it will be one of my priorities early next year, in January, February, and March, to get together again and talk about a legislative package. So your work on this is helpful.

Mr. HESELTON. Thank you, Mr. Chairman, and we will continue to pursue it.

Mr. McCLOSKEY. Thank you very much.

Now we have a return guest, Dr. John W. McVicar, Director of the Office of Biosafety, Centers for Disease Control.

If you would please make yourself comfortable, Doctor. It is good to see you again. We appreciate your expert and candid testimony last time, and I have pre-read your testimony for today. Please give it as you like, in total or comment. We will accept your written testimony for the record.

STATEMENT OF JOHN W. McVICAR, DIRECTOR, OFFICE OF BIOSAFETY, CENTERS FOR DISEASE CONTROL, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. McVICAR. Thank you, Mr. Chairman. It is a pleasure to be here.

I think, since it is rather short, I would like to read it through. I think it will perhaps go quickly.

Mr. McCLOSKEY. That is fine.

Mr. McVICAR. I am Dr. John W. McVicar, director of the Office of Biosafety, Centers for Disease Control. The Centers for Disease Control strongly supports proper packaging and shipping of all biological materials and, in particular, any material that may contain an etiologic agent.

The current system appears to be working quite well, but improvement may be possible. The packing and shipping of etiologic agents, diagnostic specimens, and biological products is regulated

by three Federal agencies: the Public Health Service through CDC, the Department of Transportation, and the U.S. Postal Service. Currently, revisions are being proposed for all three regulations.

Under current requirements, the CDC is notified of packages of etiologic agents that are damaged. While these reports do not currently indicate any systematic problems in actual practice, a review of these reports suggests that problems could potentially arise because of the lack of knowledge or understanding of the regulations, from difficulties in interpreting them, or from disregard of the regulations. To improve the system, CDC proposes a five-point program of coordination, education, training, reporting, and enforcement.

CDC, the Department of Transportation, and the U.S. Postal Service have discussed and will continue to discuss the proposed revisions of our respective regulations. The resultant regulations will be complementary, to the extent possible, and should cause a minimum of confusion to the user. The final regulations will contain unambiguous definitions and clear instructions.

Once the revised regulations are published, there will be a nationwide effort to inform the using public of their intent. To this end, a publication will be prepared that gives clear instructions for compliance with all of the regulations. The publication will be widely distributed so as to reach those who ship, handle, and receive such material. Distribution will include professional groups, laboratories, and manufacturers and distributors of packaging materials.

Training materials will be prepared covering the proper packaging and handling of etiologic agents and made available to anyone who packs, ships, receives, or otherwise handles such material.

The current regulation requires that packages of etiologic agents have a label advising those who observe damage or leakage to call CDC. This requirement will be reemphasized in the proposed education effort. As it is, handlers and receivers of damaged packages have an incentive to report them to CDC, and our records indicate that they do. In reality, these are the only people who are in a position to see and report these incidents.

Our records indicate that most shippers of diagnostic specimens and etiologic agents do comply with the regulation. We expect, on the other hand, that compliance will be improved by the previously mentioned actions. Criminal sanctions are available to us in existing law should violations be recognized. The regulations will be revised to clarify that these sanctions do, indeed, exist. Our past experience suggests, however, that leaky packages are more often caused by some extraordinary circumstance, such as being driven over by a truck, and not by inadequate packaging.

CDC has a record of reacting promptly and effectively to a variety of public health problems, and we will move quickly to deal with violations of this regulation that might endanger the health or safety of those exposed to packages of etiologic agents.

Mr. Chairman, this concludes CDC's prepared statement. I will be glad to try and answer your questions if I can.

Mr. McCLOSKEY. Thank you very much, Dr. McVicar. Welcome back again. I appreciate your work on this, and I would say your statement ties in very well with Mr. Heselton's.

Could you give me some idea of a schedule on your new regulatory and enforcement package and so forth? Is February too much of a strain?

Mr. McVicar. No, I wouldn't think so. I would think by that time, Mr. Chairman, that we would certainly have the regulatory package in hand. We will, of course, have to work out the details of providing the printed material. The training materials may be in the form of slides or tapes or the like, and sometimes these take a little doing to get them made properly. But I would certainly hope that the first phases of the education effort would be well under way by spring.

Mr. McCloskey. I would be very hopeful, as I previously indicated, of sitting down come February—before, if you like—but sitting down with you and Mr. Heselton and other expert people to go over this package in detail, point by point. Maybe we could bring Senator Levin in, with all the work that he has done on this issue.

Mr. McVicar. That would be fine, Mr. Chairman. I know Senator Levin does have an interest in this area.

Mr. McCloskey. Now it says under current requirements the CDC is notified of packages of etiologic agents that are damaged. But, in your previous testimony, you indicate that doesn't always occur, given the irregular pattern of education, and expertise, and training in the field.

Mr. McVicar. Yes. Of course, it is very difficult for us to assess the efficacy of the program. It is a reactive sort of program. We react to the packages about which we are informed.

Mr. McCloskey. When we spoke at the last hearing, you mentioned quite candidly—and this is not a criticism of you or the agency—that the regulations were there, sanctions were there, but there was no one in charge of enforcement of the regulations. I guess today, in effect, you admit the legitimacy of my concern for that.

I don't have any simple answer—I am not out in the field—as to how they could or would be enforced. But I guess one of the questions I would ask as to an improved enforcement package is, could there be the assignment of x number of staff as far as random and unannounced inspections in key areas, inspection and critiques of educational programs, and so forth? Again, if you have the law with no one, in effect, in charge of enforcement, I think that is a problem. That would be one of the modest contributions I would like to make on this dialogue.

Mr. McVicar. Yes, I think, Mr. Chairman, this would always be possible, given the resources. I think that looking at educational programs and that sort of thing might well be a feasible goal. As I think the Postal Service has rightly pointed out, it is really impossible to check on the system before the fact in terms of examining the types of packaging that are really out there.

But I think basically our hope and the thrust of our program is that, given the proper education and given the proper training, all of the people that handle these packages have a vested interest in getting them through in good condition—the people that ship them, the people that handle them, and the people indeed that receive them. I think given the proper education and training, the enforcement aspect will become, I am confident, diminishingly

small. I think that still has to be there, but I think that it would become less of a problem for all of us.

Mr. McCLOSKEY. Do you have any specific concerns for improvements as to shipments of defensive chemical and biological and etiologic agents by the Pentagon?

Mr. McVICAR. Yes. It is my understanding, Mr. Chairman, that, by and large, these materials do move by private carrier, as I think DOD has pointed out. One thing that could be mentioned, and that is that certain of the organisms that have been mentioned as biological warfare agents are warfare agents by virtue of their method of handling and delivery, if you will, by whoever is using them nefariously and that some of these same agents can be handled relatively safely in the small amounts that are sometimes transferred from lab to lab.

But I think that certainly there is a public concern and a very real one here, and certainly any regulation should take into account the class 3 and 4 agents that might be of particular danger to the public.

Mr. McCLOSKEY. Class 3's, at least, go through the mails, according to their own statements.

Mr. McVICAR. Yes, the class 3's and some class 4's possibly, but most of these are shipped by private carrier. Again, the law at this point would allow them to with special requirements. These are the ones that require tracking and a return call to make sure that they are delivered and that sort of thing.

But in actual fact I am told—and in CDC, of course, we don't deal with biological warfare type of agents—but I am told that by and large when DOD is transporting these, they do it by courier or by some other means.

Mr. McCLOSKEY. Would it be unreasonable for me to ask you if either you or someone under your jurisdiction could give a qualitative and neutral report as to transportation of the DOD materials?

Mr. McVICAR. I don't really think that we would have that information. That would be available, as far as I know, only through the Department of Defense.

You may be referring to packages that we transfer between CDC and USAMRIID, for example. These are part of Government contracts but not part of biological warfare. These we do keep track of, and we have someone on our staff—not a person, but our entire staff is concerned with this in that they are properly handled.

Mr. McCLOSKEY. So you would say your jurisdiction for the public health ends where the assertion of national security begins.

Mr. McVICAR. I think only to the extent that ours would end in terms of defining the agents and describing how the agents, under certain definitions, are transferred.

Mr. McCLOSKEY. I guess my hopes would be, quite frankly, for a positive and neutral analysis of the risk. With all due respect, I think the DOD came into our hearing with a certain point of view, not that their answers weren't to some degree comprehensive and candid; but there were some problems in their stated and open testimony that I would think a CDC person could see.

Mr. McVICAR. I would think perhaps, Mr. Chairman, the problems were more in perception than reality. This is, of course, a very inflammatory—if that is the right word—issue of biological

warfare and what constitutes a biological warfare weapon. This, as I say, I believe, is more a problem of definition than anything.

Mr. McCLOSKEY. I guess what I am thinking of is when the Pentagon spokesman—excuse me for not having his name right here—and this is no criticism of him, he did a good job—but when pressed he would say the emphasis was along the lines: "You can have these materials in a jet plane crash against a mountain, and every particle of the plane will be gone and there will be no human life aboard, but that canister will be perfectly intact, floating to the safe shores of whoever is going to pick it up below."

I think a key point is the fact that he said, "Yes, some of these organisms do live and can live outside their immediate environment." After all, the stress was that they are going to die in the canister immediately with the first pop of air, or never be able to get off the gauze.

I, as a layman, would like to know what can get off the gauze and what can travel and reproduce. I think the CDC would have a good idea of what could get away. Is that unreasonable? I don't know if they will tell me. I am on the Armed Services Committee, but I don't know if they will tell me what could get away.

Mr. McVICAR. Yes, I understand that. But what I am suggesting to you is that perhaps we have already done this in terms of describing and classifying the organisms at least with which we are familiar, the ones that are out there.

You could take, for an example, an organism like the anthrax bacillus. This is often referred to as a biological warfare agent. This is one that will survive in nature, but it is out there in nature. This is not a unique organism. It becomes a weapon when it can be produced in quantity and delivered in a crucial area. So this is what I am saying. I think that CDC, in concert with NIH, has described the hazards that are likely to be incurred in handling the various organisms that we have, that we know about in our list.

Our experience with DOD has been that they have always been extremely careful in terms of handling any organism. Actually, we will be meeting next week up the road in Bethesda at a biological safety conference. The whole concept of biological safety was actually born at USAMRIID. They are almost the folks that invented high containment, and they do it very well, and our experience has been that they are extremely well versed in handling organisms that need special handling.

Mr. McCLOSKEY. I am not arguing. I am, I think, posing some intriguing questions. But, in all candor, it makes little difference to me whether anthrax was around in the time of Moses or whether it can be found in certain parts of whatever Third World country, or a worse substance in some sort of common contagious mode. The question is the responsibility of the groups in handling these materials, and regardless of if they are elsewhere on the planet, the fact that they are elsewhere on the planet doesn't give any justification for letting them out of a box in any particular case. I just find the arguments with those analogies very intriguing, quite frankly.

Mr. McVICAR. Yes, and I understand that, Mr. Chairman. I am not really trying to evade the issue.

Mr. McCLOSKEY. No, I know you are not. I am just trying to come to grips with this myself. The fact that Moses may have seen an-

thrax—you really didn't go to the point of the hearing for me last time.

Mr. McVICAR. That is a good point. But, again, I think it relates back to the fact that transport of such organisms is often in very small quantities and very well handled, and it is just not our perception that the risk is great.

Mr. McCLOSKEY. Doctor, could you be specific about discussions which you have had with DOT and the Postal Service concerning revising existing regulations? Generally—I won't say specifically, given the elements of time—what changes would be made concerning definitions and procedures?

Mr. McVICAR. I can only answer that in general terms from our perspective. What has happened is, we have discussed this with representatives of both of those agencies. We have given each other copies of our proposed regulations, I think particularly with an eye to each one of us bringing to bear his own particular area of expertise and to come up with a set of regulations that would not be conflicting in any way but hopefully would be complementary to each other.

As far as the specifics, our particular revision is in a stage now where I can't comment on it at this point in specifics in that it is nebulous enough at this point, but we are exploring these particular sticky points in terms of definition and so forth. These become very difficult in the regulatory milieu, and we are working very hard to come up with unambiguous definitions, and we will be glad to share these with the other people.

Mr. McCLOSKEY. Would you consider specifically assigning enforcement staff?

Mr. McVICAR. I am not sure. We are in conference with our own legal staff at this moment as to how, actually, this process would work. Many times, as we discussed in our previous meeting, these locations are remote from CDC, and often the reporting person is a postal employee or a public carrier or someone in some other area, and we need to figure out how this information is going to get to us and how we proceed.

I think it is clear that if, indeed, there is evidence of some flagrant violation of the law, that the law is there and can be brought to bear.

Mr. McCLOSKEY. Have there ever been any criminal sanctions pressed in this regard?

Mr. McVICAR. No, sir, not to my knowledge. Now that is through our public health law. I am not sure whether the Postal Service or the Department of Transportation has.

Mr. McCLOSKEY. And, again, right now you cannot tell me how CDC, per se, will improve enforcement other than in the general terms we talked about?

Mr. McVICAR. That is correct at this point. We hope to outline that in the more revised edition of the regulations.

Mr. McCLOSKEY. Can you state general or specific goals and programs for training as to postal employees? Would CDC be going out in the field all over the Nation, or would you be concentrating on training experts within the postal system and letting them go back and do it?

Mr. McVICAR. I think either or both would be possible means of getting this job accomplished.

Also, it has been our experience that properly conceived and well made audio-visual materials can go a long way, producing videos and slide sets that are very informative along with a presenter. You then launch into a train trainer program, and you should be able to get the word out, I think, well and do it properly and get it done right.

The material you have to present is not terribly technical or complicated, and I really think some means of—perhaps the booklet, in itself, will do most of it, because, as I say, we get the questions, people asking us, "How can I do it better?" and I think that is what the education program will address.

Mr. McCLOSKEY. Have you been actively helping the Postal Service on their interim program as we get this all worked out?

Mr. McVICAR. We haven't yet. We have been in conversation with them specifically now in terms of trying to mesh the regulations at this point.

Mr. McCLOSKEY. Okay. Thank you very much for your excellent testimony, Doctor. I look forward to meeting with you early in the year. Would you have any concluding observations or any area you would like to talk about that I haven't covered?

Mr. McVICAR. No. I think we have covered the ground. I would be happy to come back whenever, and we will keep you informed of our progress in this very important area.

Mr. McCLOSKEY. Well, if I am not here next year it won't be because I didn't try. I would hope to see you next year.

Mr. McVICAR. We wish you luck in that regard.

Mr. McCLOSKEY. Thank you. Thank you, Doctor.

Now we have Dr. Jesse Tucker of the Association of State and Territorial Public Health Laboratory Directors.

Good morning, Dr. Tucker.

STATEMENT OF JESSE S. TUCKER, ASSOCIATION OF STATE AND TERRITORIAL PUBLIC HEALTH LABORATORY DIRECTORS

Mr. TUCKER. Good morning. Thank you for this opportunity.

My name is Jesse Tucker. I am chief of the Bureau of Laboratories of the Connecticut Department of Health Services, and I am here on behalf of the Association of State and Territorial Public Health Laboratory Directors.

The health of America relies to a great extent upon a surveillance system which includes safe and rapid transport of biological materials to State health laboratories for analysis and subsequent diagnosis of human abnormalities. The quality of these laboratory analyses depends upon the same transportation system for the shipment of quality control materials similar in nature to diagnostic specimens. The system described is presently available and has been transporting biological materials for decades to State health laboratories without serious consequences to laboratory employees or to employees of the United States Postal Service and other carriers.

This does not mean that these shipments have been without incident. Several State health laboratory directors have been notified

by local postal authorities of packages whose contents have leaked sufficiently to penetrate the outside of the shipping containers. However, I am aware of no case where leakage occurred when specimens were properly packaged in water-tight containers and adequate absorbent material was provided. In many cases, the State health laboratory was neither the shipper nor the recipient of the material.

Because of these incidents, some local postal authorities have mistakenly concluded that all biological materials are etiological agents and required them to be packaged and labeled as such. The Postal Bulletin of August 1, 1988, includes a notice and exhibit in 121.56 which also appeared in the Domestic Mail Manual, issue 28, requiring that packaging required for etiological agents also be used for the packaging and shipment of biological materials.

My colleagues and I agree that the materials which we handle should be properly packaged, labeled, and shipped primarily via the reliable United States mail. We agree that all those who handle these materials should be properly protected. We agree that the laws provided for such shipments should be enforced on a universal rather than on a local basis. We believe that the laws concerning packaging and shipment of the materials, which our employees also handle on a regular basis, be written clearly to avoid misinterpretation. We volunteer our services to work with those drafting such laws as well as with those handling the materials in transport to understand and improve on an already safe and effective system.

A major deterrent to a consistent, safe, and efficient system is created by the terminology used in Federal laws—42 CFR 72 and 49 CFR 171—and in the Domestic Mail Manual. This terminology prevents a reasonable distinction between a diagnostic specimen and an etiological agent. Laboratory directors do not believe that properly packaged materials which are transported to and by them will kill, injure, or infect those transporting such items. They are unaware of any instance in which such an event has occurred. On the other hand, they also believe that the transporter should not have to contend with packages that have leaked contents, whether the leaking fluid is blood, urine, other body fluids, or materials used for cooling.

More precise definitions of such terms, such as "etiological agent" and "biological specimen" and removal of equivocal terminology, including whether a "person reasonably believes" that the specimen may contain an etiological agent, as indicated in 42 CFR 72.2, would go a long way to resolve current misunderstandings and result in better compliance with regulations.

Health laboratories do believe that a safe, simple, and cost-effective packaging system is available for biological materials. They believe that those specimens, cultures, and proficiency testing materials needing special packaging and labeling should be so defined. They are anxious and willing to assist in drafting laws, educating laboratory employees and postal workers, and in enforcing the requirements of these laws.

In the absence of a transportation system provided by the U.S. Postal Service, the consequences could be disastrous. Inability to transport blood specimens safely and inexpensively, which includes

those noninfectious specimens tested for phenylketonurea, otherwise known as PKU, and lead poisoning, could seriously hamper important programs which prevent mental retardation in children. Control of sexually-transmitted diseases would be more difficult. Detection of new infectious agents, such as the bacterium responsible for Legionnaires' disease, would be inhibited and delayed. The cost of shipping these materials could rise dramatically if more dependence had to be placed on private shippers.

In conclusion, the Association of State and Territorial Public Health Laboratory Directors is committed to a safe, efficient, and enforceable system for transporting biological materials, including specimens, cultures, and etiological agents. We believe that such a system is essential to public health. We believe that the basis for such a system already exists and that improvements can be made to ensure the safety and health of all of those involved in their transport. We look forward to the opportunity for a cooperative effort to further develop such a system.

Thank you very much.

Mr. McCLOSKEY. Thank you very much, Dr. Tucker. Your entire statement has been accepted for the record. We appreciate your being here today.

Other than your statement, I believe you probably heard all or most of the discussion with the previous two witnesses. Are there any highlights or emphasis you would like to briefly add or suggest?

Obviously, you say that when there has been good and proper packaging, there are, in essence, no reports of potentially significant problems. I think that is one of the problems that our hearings have revealed. Often there are defects in the packaging and transportation processes—things smashing in bulk mail centers and accidents occurring. What would you really like to highlight today with several key points?

Mr. TUCKER. The one thing that I would like to highlight: I have been working this area for almost 15 years, and I have worked with packaging of etiological agents for about 4 years. I think that you will find that once the difficulties in language are rectified and once the laboratory directors know what it is definitely that is wanted, you will have about 55 people out there who are going to be only too happy to help you do what is necessary to make this a more safe and efficient system.

Mr. McCLOSKEY. Has your association been invited to participate in any way by the CDC or the Postal Service?

Mr. TUCKER. Yes, we have been participating.

Mr. McCLOSKEY. That is very good. I appreciate that.

You mentioned that several State health laboratory directors have been notified of packages whose containers have leaked sufficiently to penetrate the outside of the shipping container. Do you know what material was leaking?

Mr. TUCKER. Usually it was a blood specimen sent in, most usually for something like testing for syphilis serology. So it usually was a blood specimen. However, there have been other instances where the leakage was actually the ice that was used to surround the package.

Mr. McCLOSKEY. Do you know of any instance where criminal or other legal penalties have been pressed, given bad packaging or noncompliance with the procedures?

Mr. TUCKER. No, sir.

Mr. McCLOSKEY. Would you comment on my concerns—and I think Dr. McVicar shares them now—as to improving the enforcement process, to say nothing of education. Don't you think there could be cause for some regular inspection and enforcement system other than just operating on a complaint or incident basis?

Mr. TUCKER. I believe that any law that cannot be enforced is not a very good law, so that I do believe that there should be penalties. However, I also do believe that the need for them will be very small once the problem has been resolved.

Mr. McCLOSKEY. It is probably not your stated area for being here, but I assume you have the technical expertise to know generally the types of substances, biological and chemical and medical, that go in the mails. Do you have any ideas as to any substances that should not be transported in the mails, DOD-derived or otherwise?

Mr. TUCKER. The materials that we handle I do not believe would be so dangerous that they could not be handled by the United States mails. I am not that familiar with the other types of substances.

Mr. McCLOSKEY. I appreciate that. I think it is obvious to all of us right now, including the Postal Service, that a total ban on etiologic agents isn't likely to occur. I don't know if the Postal Service really intended that, but I think it is safe to say it got a lot of attention as to the concerns for the problem. Right?

Mr. TUCKER. You are right, sir. It certainly did.

Mr. McCLOSKEY. Is there anything else you would like to add, Doctor?

Mr. TUCKER. No, sir. Thank you very much.

Mr. McCLOSKEY. I hope to be working with you next year then. I appreciate your coming all this way. Thank you.

Now we have a panel of three witnesses: Dr. Thomas Gavan, Member of the Commission on Scientific Resources, the College of American Pathologists; Dr. Robert C. Rock, Member of the Board of Directors of the American Society of Clinical Pathologists; and Dr. Pierre-Marc Daggett, Chairman of the Committee on Culture Collections of the American Society for Microbiology.

I want to thank you for being here today, gentlemen, with your expert observations and your willingness to help the committee and the Congress. I will accept all prepared statements—I know there are several—for the record. I will let you fight it out as to order and precedence, however you want to do it.

STATEMENT OF THOMAS L. GAVAN, M.D., MEMBER, COMMISSION ON SCIENTIFIC RESOURCES, COLLEGE OF AMERICAN PATHOLOGISTS

Dr. GAVAN. I am Dr. Gavan, Mr. Chairman. I am a board-certified physician specializing in pathology, and I am the chairman of laboratory medicine at the Cleveland Clinic Foundation in Cleveland, Ohio. I have a particular interest in the issue at hand today. I

serve on the College of American Pathologists' Surveys Committee, as well as the CAP's Commission on Scientific Resources, as well as the CAP, CDC, and HCFA Equivalency Working Group. I am also the past president of the National Committee for Clinical Laboratory Standards.

The College shares concerns of the Postal Service over the safety of transporting material containing etiologic agents. As physicians and as the organization that has, for the past 25 years, conducted the largest and most comprehensive proficiency testing program, we take particular interest in the safety and health precautions fundamental to the safe exchange of medical materials.

We believe that the Postal Service's proposed ban will take in two categories of medical materials that we believe do not pose a health threat when properly labeled and packaged and for which a lengthy and documented record of safe transport exists.

The first area of College concern is the exchange of diagnostic specimens between physicians and/or laboratories. In the course of consultation or for additional or reference testing, physicians and laboratories routinely send specimens which may contain etiologic agents to another physician or laboratory. Typically, the agents involved are of everyday occurrence—for example, those that may cause strep throat or various gastrointestinal infections. A ban on the exchange of these specimens would impose a serious and, we believe, unwarranted impediment to diagnostic consultation.

Also severely affected by the proposed rule would be State and local health departments, the Centers for Disease Control, and research facilities as well as hospitals and independent laboratories, all of which have regular need to send or to receive specimens which may contain etiologic agents. Even if an alternative transport mechanism can be found—and in some small and rural communities that may be impossible—the costs of shipment could exceed the cost of the performance of the test procedure itself.

Our second concern is laboratory proficiency testing. CAP proficiency testing materials, some containing etiologic agents but all labeled and packaged according to HHS rules, have been safely transported by U.S. mail for 25 years without a single instance of injury or illness. That safety record can be credited to a number of factors. One is the strict Department of Transportation and HHS packaging requirements which were developed by an expert panel which included DOT, PHS, air cargo personnel, airline pilots, medical specialty organizations, microbiology experts, and laboratory representatives. This package requirement has been approved through a consensus process, in which I myself participated, of the National Committee for Clinical Laboratory Standards. This standard has subsequently been adopted as the United States national standard by the American National Standards Institute in 1985.

Another safety factor lies in the form of the proficiency testing samples. All College proficiency testing samples containing etiologic agents, except for two, are sent in the dry state, and they are incapable of causing illness even if disturbed. The two exceptions shipped in a liquid state have been previously inactive and are also rendered noninfectious.

In order for dried specimens to be infectious, they would have to be rehydrated, maintained under suitable temperature and atmos-

pheric conditions, and either ingested, injected, or otherwise absorbed into an appropriate body site which would be suitable to facilitate growth and reproduction of the specific organisms. Additionally, the CAP and other proficiency testing organizations do not mail etiologic agents for diseases for which there is no cure or readily available medical treatment.

In addition to the CDC emergency telephone system, the College also maintains a 24-hour telephone line for inquiries on damage of any sort from postal employees, from package handlers, and/or the receiving laboratories. Readily available are a list of physicians and treatment protocols for every agent in the CAP program. While primarily designed to protect laboratory personnel, the CAP system also protects postal workers and transportation employees since it provides for immediate identification of the package's content and a recommended action.

For etiologic proficiency testing materials barred from the mail, the College estimates that the cost for private carriers would increase CAP's shipping costs several hundred percent and, at the same time, ultimately the costs to CAP proficiency testing participants from a minimum of near $150,000 to perhaps over as much as $2,000,000 per year. Ironically, Congress is close to passage of a laboratory quality assurance bill that would expand proficiency testing and require it for all laboratories, including those in physicians' offices. Without the use of the U.S. mail to send required periodic samples for testing, the cost to the Government and to laboratories could result in fewer laboratories able to qualify under Federal regulations, thereby constricting the availability of health care for the American public.

The College of American Pathologists offers the following recommendations: that the shipment of medical diagnostic specimens and laboratory proficiency testing materials continue to be permitted in the U.S. mail under current strict labeling and packaging regulations; that the shipment of biological warfare agents and those which are extremely virulent and for which there is no cure or readily available medical treatment be treated as a separate issue from that of medical applications; that the enforcement of current labeling and strict packaging requirements for etiologic agents be strengthened; that education of postal workers, the public, the medical community, and other potential shippers be augmented. Emphasis should be placed on labeling and packaging requirements as well as the consequences for lack of compliance. The College would be pleased to assist in this educational effort.

Finally, the CAP recommends that the Postal Service convene a consensus conference of involved organizations to review current requirements and to determine the appropriate safeguards for the necessary shipments of medical etiologic agents.

We would like to reaffirm our strong support for the laboratory community consensus comment sent to the Postal Service by 13 organizations, including the College, urging review and enhancement of existing regulations through the establishment of a Federal Interagency Committee and through education, training, and enforcement.

The College of American Pathologists appreciates the opportunity to comment and pledges continued support and expertise of our

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medical specialty to assure the postal employees and the public are protected from health risks in the routine and necessary shipment of medical etiologic agents.

Thank you very much. I will be glad to answer any questions.

[The statement of Dr. Gavan follows:]

College of American Pathologists

Testimony of the
College of American Pathologists

October 5, 1988

Before the
Subcommittee on Postal Personnel and Modernization
On the
Transportation of
Biological Toxins and
Etiologic Agents Via the United States Mail

Presented by:

Thomas L. Gavan, MD
Member, Commisssion on
Scientific Resources
College of American Pathologists

COLLEGE OF
AMERICAN PATHOLOGISTS

The College of American Pathologists, a medical specialty society composed of 10,500 physicians who practice pathology in hospital and independent laboratories and in teaching centers, appreciates the opportunity to testify on the transportation of biological toxins and etiologic agents via the U. S. Mail.

Our membership shares the concerns of the Postal Service over the safety of transporting material containing, or suspected to contain, etiologic agents. As physicians and as the organization that has for the past 25 years conducted the largest and most comprehensive interlaboratory comparison (proficiency testing) program, we take a particular interest in the safety and health precautions that are fundamental to the safe exchange of medical materials.

We concur with the Postal Service's concern, voiced in this Subcommittee's June 23 hearing, that extremely virulent agents, particularly those for which there is no readily available medical treatment or cure, could pose a transportation hazard, and we believe these agents should be treated in a separate manner and with utmost caution for the protection of postal workers and the American public.

We believe, however, that the Postal Service's proposed ban will take in two categories of medical materials: 1) those used in laboratory proficiency testing and 2) those exchanged by physicians and laboratories for consultation or testing, that do not

pose a health threat when properly labeled and packaged and for which a lengthy and documented record of safe transport exists. We have thus recommended that the Postal Service separate these categories as different from that of the most dangerous and extremely virulent etiologic agents.

Impact on Physicians, Independent, Hospital, and Research Laboratories in Sending Diagnostic Specimens for Consultation and Testing

The first area of College concern is the exchange of diagnostic specimens between physicians and/or laboratories. In the course of consultation or for additional or reference testing, physicians and laboratories routinely send specimens which may contain etiologic agents to another physician or laboratory. Typically, the agents involved are of everyday occurrence -- those that cause strep throat or gastro-intestinal infections, for instance.

Under the Postal Service proposed rule, specimens that are from a febrile patient and are suspected of having a bacterial or viral origin, even if properly labeled and safely packaged, would be prohibited from the mail. This kind of rule would impose a serious and unwarranted impediment to diagnostic consultation. Also severely affected by the proposed rule would be state and local health departments, the Centers for Disease Control, and research facilities as well as hospital and independent labora-

tories, all of which regularly have need to send or receive specimens which may contain etiologic agents. Even if an alternate transport mechanism can be found, the costs of shipment in some cases would exceed the cost of the performance of the procedure.

In small communities not served by private couriers, impaired access for the routine exchange of medical diagnostic specimens would raise serious health concerns for patients. In that situation, the loss of timeliness and the possibility of unregulated transport of these specimens could result in a breach of quality in the chain of medical testing. The role of the Postal Service in requiring and enforcing strict packaging and labeling of medical etiologic agents is in itself a safety measure to which patients should have access. Implementation of the proposed ban, aimed at safety, could in fact jeopardize the proper treatment of patients requiring testing or diagnostic consultation.

Impact on Proficiency Testing Programs for Laboratory Quality Assurance

CAP proficiency testing materials, some containing etiologic agents, but all labeled and packaged according to Department of Transportation and Health and Human Service rules, have been

safely transported by U.S. Mail for 25 years without a single instance of injury or illness.

In his testimony June 23 before subcommittees of the Committee on the Post Office and Civil Service and the Committee on Armed Services, the Director of the Office of Biosafety, Centers for Disease Control, said that over the past 9 years, calls to the CDC on verified damaged packages containing etiologic agents have averaged three per year. Of that number, "none resulted in a reported infection." Testimony by the Assistant Postmaster General confirmed that: "There have been no reported instances of any postal employees suffering from injuries from handling these [etiologic agent] materials."

That safety record can be credited to a number of factors. One is the strict DOT and HHS packaging requirements, which were developed by an expert panel which included DOT, PHS, air cargo personnel, airline pilots, medical specialty organizations, microbiology experts, and laboratory representatives. This packaging requirement has been approved through a consensus process of the National Committee for Clinical Laboratory Standards and was adopted as a U.S. National Standard by the American National Standards Institute (ANSI) in 1985.

One extreme example points out the security of the packaging based on those standards: on receiving a phone call from a New York

airport about a damaged CAP package, it was discovered that the package had fallen from a baggage cart and been run over by a forklift. While the outer package was damaged and the inner can flattened, the innermost vials containing the etiologic agents were undamaged.

Another safety factor lies in the form of the proficiency testing samples. All College proficiency testing materials containing etiologic agents, except two, are sent in a dry state, and without appropriate conditions, they are incapable of causing illness even if disturbed. In order for lyophilized (dried) specimens to be infectious, they would have to be rehydrated; be maintained under suitable temperature and atmospheric conditions; and either be ingested, injected, or otherwise absorbed into an appropriate body site suitable to facilitate growth and reproduction for the specific organism. Additionally, the CAP and other proficiency testing organizations do not mail etiologic agents for diseases for which there is no cure or readily available medical treatment. The only two CAP samples sent in serum, HIV and hepatitis, are in an inactive and noncontagious state.

In addition to the emergency phone system operated by the CDC, the College maintains a 24-hour telephone line for inquiries on damage of any sort from Postal Service employees, package handlers, or the receiving laboratories in the shipping or the processing of CAP proficiency testing samples. The College's response time to

an inquiry averages less than 2 hours. Readily available are a list of physicians, also on call, and treatment protocol for every agent in the CAP program. While primarily designed to protect laboratory personnel in the case of mishap while processing these materials, the CAP system also protects transportation employees, since it provides for immediate identification of a package's contents and recommended action. It also provides a systematic overview throughout the entire shipping process by the CDC and the organization sending the material. This valuable overview would be lost if the Postal Service did not continue its vital role in regulation and enforcement.

Were etiologic materials barred from the mail, the alternative for organizations operating proficiency testing programs, including the CDC and several state public health agencies, would be private couriers. The added expense could make proficiency testing prohibitive for smaller laboratories in particular. The College estimates that the cost for private air carriers would increase CAP's shipping costs several hundred percent and ultimately costs to proficiency testing participants from $150,000 to over $2,000,000 per year depending on the costs of alternate transportation sources.

Ironically, Congress is currently considering two laboratory quality assurance bills that would require proficiency testing for all laboratories, including those in physician offices. Without

the use of the U.S. Mail to send the required periodic samples for testing, the cost to the government and to laboratories could result in fewer laboratories able to qualify under federal regulations, thereby constricting of availability of health care for the American public.

College Recommendations

Based on more than 25 years of experience in the processing and handling of medical etiologic agents, the College of American Pathologists offers the following recommendations:

1) The CAP recommends that the shipment of diagnostic specimens which contain or could contain etiologic agents continue to be permitted in the U.S. Mail under the current strict labeling and packaging regulations.

2) The CAP recommends that proficiency testing materials likewise be allowed to continue to be shipped via the Postal Service.

3) The shipment of biological warfare agents or those that are extremely virulent or those for which there is no cure or readily available medical treatment is a separate issue which deserves singular consideration by the Postal Service. We believe that the routine

shipment of medical etiologic agents does not belong in the same category of restriction.

4) We recommend the strengthening of enforcement by the Postal Service of the current labeling and strict packaging requirements for etiologic agents.

5) We also urge the augmentation of education of Postal workers, the public, and the medical community. Education is the essential precursor to enforcement. We believe that materials should be developed to train Postal employees and, separately, to educate the medical community and other potential shippers. Emphasis should be placed on detailing of the requirements as well as on the consequences for failure to comply with shipping regulations. The College would be pleased to assist in this effort and believes that earlier discussion of a videotape by CDC and the Postal Service is an excellent idea that should be realized.

6) Finally, the CAP recommends that the Postal Service convene a consensus conference of involved organizations with special interest or expertise to determine the appropriate safeguards for the necessary shipment of medical etiologic agents. Should such a review determine that sufficient concern remains over the quantity

of material which may be shipped, the packaging, or the classes of organisms, the CAP would be pleased to work with Postal personnel and other interested organizations to review current requirements and develop appropriate modifications to alleviate those concerns.

Attached to this testimony is a consensus comment sent by the College, the ASM, and 11 other organizations offering the recommendations and support of the laboratory community for the safe transport of etiologic agents. We reaffirm our strong support for review and enhancement of existing regulations through establishment of a Federal Interagency Committee and through education, training, and enforced penalties.

The College of American Pathologists appreciates the opportunity to comment on this issue and pledges continued support and the expertise of our medical specialty in efforts to assure that Postal employees and the public are protected from health risks in the routine and necessary shipment of medical etiologic agents.

PUBLIC AND SCIENTIFIC AFFAIRS BOARD

AMERICAN SOCIETY FOR MICROBIOLOGY

1913 I Street, N.W.
Washington, D.C. 20006
(202) 833-9680

August 22, 1988

Donald D. Dillman, Director
Office of Classification and
Rates Admisnistration
Rates and Classification Department
475 L'Enfant Plaza West, SW
Room 8430
Washington, DC 20260-5360

Dear Mr. Dillman:

The U.S. Postal Service, through providing the mechanisms for the shipment of etiologic agents and diagnostic specimens, has significantly contributed to the public health and well-being of the nation: clearly, continuation of this function is essential. The most efficacious method of shipment of the agents is by proper packaging and shipping through the U.S. mail as delineated by current regulations (42CFR Part 72) as promulgated by the Public Health Service (PHS) [Centers for Diease Control (CDC)]. The current consensus standards were developed by the National Committee for Clinical Laboratory Standards (NCCLS) based on the PHS [CDC] regulations. The relevant NCCLS standard is HS-A2, Procedure for the Domestic Handling and Transport of Diagnostic Specimens and Etiologic Agents - 2nd Edition. This standard was published by NCCLS in January, 1985, and was adopted as an American National Standard by ANSI in July, 1985. The use of current packaging and labeling procedures has proven to be safe and cost-effective. It is in the best interest of all, shippers, handlers, and recipients, that the shipment of such material continue to be both safe and cost-effective.

It is not unwarranted that current regulations be periodically reviewed, but in doing so, we request that the U.S. Postal Service consider the following:

1) That the PHS [CDC] and the Department of Transportation (DOT), both involved with various aspects of regulation in the shipment of etiologic agents and diagnostic specimens, are considering revisions to current regulations. It is recommended that the U.S. Postal Service participate with the PHS (CDC) and DOT in forming a federal interagency committee to review the appropriateness of current regulations for packaging and shipping etiologic agents and

diagnostic specimens so that guidelines/regulations may be established. It is also recommended that this committee seek the participation of nongovernmental organizations to assist in providing expertise and comment prior to the publication of proposed regulations. It is further encouraged that the interagency committee remain in existence to periodically review regulations thus ensuring safe and cost effective transport of etiologic agents and diagnostic specimens.

2) That there be initiated a review of definitions describing etiologic agents and diagnostic specimens to identify more precisely potential risk(s) and define packaging requirements. Current terms and definitions have caused some confusion. It is unclear, for example, what should be considered a diagnostic specimen, and in turn, when that specimen should be labeled an etiologic agent. The term etiologic agent is broad and does not segregate hosts and levels of potential risk. More appropriate terms and accurate definitions would greatly improve the current system.

3) That there be established an education and training program for shippers, handlers, and recipients of etiologic agents and diagnostic specimens that emphasizes compliance with regulations, proper packaging and shipping. The program should involve governmental and nongovernmental organizations in order to educate the broadest possible range of individuals. The College of American Pathologists, the NCCLS, the American Society of Clinical Pathologists, and the Association of State and Territorial Public Health Laboratory Directors are important organizations that should be called on to assist in the development of such a program.

4) That there be enforcement with penalties for those who violate regulations on the shipping and packaging of etiologic agents and diagnostic specimens. Penalty actions must be made widely known. Procedures for prosecution of violators should be clearly established by the proposed Federal Interagency Committee. These procedures should be made known not only to postal employees but also to all those who ship agents and specimens through the mail.

Current regulations on the shipping of etiologic agents and diagnostic specimens through the U.S. mail have been successful and safe when properly followed. The course of action we have recommended can lead to an even better, safer system.

We are prepared to meet with the U.S. Postal Service to elaborate upon these proposed recommendations. To that end, we the undersigned express our willingness to assist the U.S. Postal Service, in any capacity, in implementing these recommendations for the enhancement of the current system.

Sincerely,

American Association for Clinical Chemistry
American Association of Blood Banks
American Clinical Laboratory Association
American Public Health Association
American Society for Cell Biology
American Society for Microbiology
American Society of Clinical Pathologists
Association of Systematic Collections
American Type Culture Collections
Becton Dickerson Microbiology Systems
College of American Pathologists
National Committee for Clinical Laboratory Standards
State and Territorial Public Health Committee

Mr. McCLOSKEY. Thank you very much, Doctor, for an excellent statement. I think we will have general discussion after we hear from your two colleagues.

Please proceed.

STATEMENT OF ROBERT C. ROCK, M.D., MEMBER, BOARD OF DIRECTORS, AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

Dr. ROCK. Mr. Chairman, my name is Dr. Robert Rock. I am director of laboratory medicine at the Johns Hopkins Hospital in Baltimore, Maryland. The Laboratory employs 320 laboratory professionals ranging from clinical laboratory technicians to pathologists and other physicians. I am here today representing the American Society of Clinical Pathologists—ASCP—a scientific organization with a membership of over 40,000 pathologists, other physicians, medical technologists, clinical laboratory scientists, and technicians.

The importance of safely transporting etiologic agents is well recognized. However, the ASCP does not support the Postal Service's proposed ban, as published in the Federal Register, on the mailing of these agents. We do not view this as a necessary step to alleviate concern among Postal Service employees about the transmission of an infectious disease due to a leaking package. The harm to medical research, diagnosis, and continuing professional education by this proposal cannot be justified given the current packaging requirements to ensure that etiologic agents are mailed safely. We believe that strict adherence to these requirements has protected Postal Service employees from dangers in the past. Instead of imposing a ban, we believe the Postal Service's efforts could be better directed towards enforcement of the current requirements.

The ASCP supports increased emphasis on compliance with Federal standards designed to ensure that packages containing agents are safe. Specifically, the Society supports: one, a uniform Federal policy for packaging requirements; two, a review of the current packaging requirements; three, greater educational efforts to ensure that shippers are aware of packaging requirements; and, finally, four, the use of appropriate penalties against those shippers who are not following packaging rules.

I would like to explain how the Postal Service helps my laboratory. For the past eight years, we have participated in ASCP's Check Sample Program. Unlike proficiency testing programs which are required for laboratory certification, the Check Sample Program is a voluntary self-assessment for clinical lab professionals. It has served in that capacity since 1958. The exercises consist of mailed samples which test the skills of professional and accurate and precise identification of chemical substances as well as microbiologic organisms. These exercises give the laboratory and its professionals the opportunity to expand and to grow professionally as well as to keep up to date on the newest technologies.

Hopkins' participation in the Check Sample Program is twofold. We subscribe to the program for feedback and self-improvement. We have also assisted in designing questions to be used in the program by other laboratories. In my experience, this consultative

service which the program provides has been invaluable both to us and the physicians that use our laboratories.

In addition, we also act as a reference laboratory for physicians and other clinical labs. In that capacity, we both receive and mail specimens containing etiologic agents. We closely adhere to packaging requirements to ensure that there will not be any leakage during transport. A total ban on these mailings would severely reduce, if not eliminate, much of the important educational and clinical advantages which we and our physicians and their patients derive from this activity.

In over 30 years that the ASCP has administered the Check Sample Program via the mail system, we are unaware of any reports of adverse incidents affecting a Postal Service employee or the public. While the present regulatory mechanisms have, in our opinion, thus far proven to be effective in ensuring safety for Postal Service employees and the general public, we recognize that all regulations need to be reviewed for their efficacy from time to time.

The ASCP participated in the original development of these safety standards. We offer our support and assistance in any efforts that might be undertaken for a review and, if needed, an update of these regulations. Additionally, as an educational organization, the Society is willing to provide its technical expertise to provide better instructive material to those who must comply with these requirements.

Shippers of etiologic agents should comply with current Federal packaging requirements. It is important to note that the knowledgeable professionals who regularly use the postal system to transport these agents are not the primary cause of concern. These individuals generally can be counted upon to follow packaging requirements. Enforcement of appropriate packaging requirements needs to be directed toward those individuals who, by virtue of not regularly using the mail for this purpose, may not be giving adequate consideration to the public health dangers of improperly packaged shipments. These individuals need to be reminded that they have a responsibility to follow the Federal regulations so that their packages are safe for handling. Financial penalties would serve as an effective deterrent to violations.

The medical community, in general, relies heavily on the Postal Service as a participant in assuring public health. Continued education of laboratory professionals ensures that the public is afforded the most current medical services. We do recognize and appreciate the concerns of the Postal Service over the dangers of improperly packaged etiologic agents. Postal employees must be protected from such dangers. These safety concerns, however, must be balanced with the very important health care benefits derived from programs such as the ASCP's Check Sample Program.

The issue really is to ensure that this medical material is indeed packaged safely. The Society is prepared to work with the subcommittee and the Postal Service and other agencies toward the ultimate goal of safety and quality health care.

I thank the committee for this opportunity to comment and would be happy to answer any questions.

[The statement of Dr. Rock follows:]

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STATEMENT

of

THE AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS

to the

HOUSE COMMITTEE ON POST OFFICE AND CIVIL SERVICE

SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION

Re: The Transportation of Biological Toxins and Etiologic Agents through the Mail

October 5, 1988

The American Society of Clinical Pathologists (ASCP) is pleased to have this opportunity to comment on the very important function provided by the United States Postal Service in transporting biological products, diagnostic specimens and etiologic agents. On behalf of its members, the ASCP recently expressed support of current packaging requirements to assure that such transport be performed safely with minimal risk to carriers. The Society is therefore pleased to address questions regarding the efficacy of the present regulations as well as the detrimental impact of the proposed ban on the mailing of such substances.

The ASCP supports increased emphasis on compliance with those federal requirements designed to ensure that packages containing etiologic agents are safe. Specifically, the Society supports: 1) a uniform federal policy for packaging requirements; 2) a review of the current packaging requirements; 3) greater educational efforts to ensure that shippers are aware of packaging requirements; and 4) appropriate use of penalties to discourage those shippers who are not following package rules.

The ASCP opposes the Postal Service's proposed ban on shipping etiologic agents through the mail.

The use of the Postal Service to transport organisms which might potentially cause disease under some conditions is essential to maintain quality of health care throughout the nation. These mailings provide continuing education of laboratory professionals whose responsibilities include the identification and diagnosis

of such organisms and consultations thereon. In view of the essential role such mailings play in medical practice and research and the virtually perfect track record the mailing of etiologic agents has had within the medical community, the ASCP opposes the Postal Service's proposed ban as being unnecessary and indefensible.

The ASCP plays a major role in educating clinical laboratory professionals. The ASCP Check Sample Program, a voluntary self assessment test for clinical laboratory professionals, has served as an important continuing education tool since 1958. The exercise consists of the mailing of sample bacteria, almost all of which are lyophilized, to test the skills of the professional in identification of the organism. The subscriber identifies the bacteria and answers test questions.

The proposed ban on the mailing of all etiologic agents would have a devastating impact on ASCP's Check Sample Program and other education activities. A ban of such mailing would raise the Society's postage cost between 800-1200 percent depending on choice of private courier system. Such an increase in cost for voluntary continuing education materials for a non-profit organization would essentially eliminate access of scientists to this <u>important</u> offering.

<u>Example: The impact of the Check Sample Program on laboratory performance at the Johns Hopkins Hospital.</u>

The Johns Hopkins Hospital Laboratory, employing 320 laboratory professionals from clinical laboratory technicians to pathologists and other physicians, relies heavily on ASCP's Check Sample Program. Hopkins' participation in the Check Sample program is two-fold. In addition to subscribing to the program for feedback and self-improvement, the laboratory has assisted in designing questions to be used by other laboratories. The consultative service realized by the Check Sample program has been invaluable to both physicians and their patients throughout Maryland and the surrounding region.

Hopkins also acts as a reference laboratory for physicians and other clinical laboratories. In that capacity the laboratory receives and mails specimen samples containing etiologic agents. Packaging requirements are closely followed to ensure that there will not be any leakage during transport. If this program were to be terminated as a result of a Postal Service ban, the laboratory and its personnel would lose its effectiveness in maintaining the quality of laboratory services through communication with other laboratories by means of shared specimens.

Other effects of the proposal ban.

The proposed ban would have a major impact far beyond ASCP. Clinical laboratories which participate in the Medicare program and/or are licensed for purposes of interstate commerce pursuant to the Clinical Laboratory Improvement Act are required to subscribe to a proficiency testing program for quality assurance purposes. These programs are essential to ensuring high quality laboratory testing. In fact, H.R. 5150, the "Clinical Laboratory Improvement Amendments of 1988," passed by the House September 13, would expand the role of this effective mechanism. H.R. 5150 would substantially increase the number and types of laboratories required to enroll in proficiency testing to demonstrate the laboratory's testing ability. Organizations offering such programs would be economically prohibited from providing meaningful programs using specimens (etiologic agents) if the proposed ban is adopted. The end result would be a reduction in the availability of such programs and a risk to quality health care delivery.

Another major concern regarding a ban is the impact it would have on the mailing of diagnostic specimens between physicians and clinical laboratories. Physicians send patient samples to laboratories for testing when disease is suspected. Diagnostic consultation and reference laboratory testing would be severely constrained by a ban. Such a move would have a serious detrimental impact on the diagnosis and treatment of disease in the United States. This is particularly crucial in rural areas where the Postal Service is relied upon even more heavily. The alternative--using private couriers--would significantly raise the cost of health care delivery and reduce access. These extra costs would be felt most heavily by patients.

It can also be expected that the proposed ban would have a negative impact on medical research. The Centers for Disease Control (CDC) recently testified before Congress that "any action that would curtail the exchange of infectious agents between laboratories would seriously impede progress toward controlling and treating important human diseases."

Present Federal regulations governing the shipment of these materials adequately serve the purpose of protecting Postal employees and the general public.

The Postal Service presently allows the mailing of etiologic agents and diagnostic specimens or biological products suspected of carrying etiologic agents provided these items are properly prepared for mailing in accordance with regulations promulgated by the Departments of Health and Human Service, 42 C.F.R. pt. 72 (1987), and Transportation, 49 C.F.R. pt. 173 (1987). The ASCP participated in the development of these rules. The CDC has

stated that not a single illness has been reported in the nine years since its 24-hour telephone service lines to provide emergency assistance in the event of a damaged or leaking package involving an etiological agent was instituted.

While current packaging requirements have been effective, many medical related organizations such as ASCP even exceed the current requirements and mail the organisms in a suspended or freeze-dried state, thus ensuring even greater safety. In the over 30 years the ASCP has administered the Check Sample Program via the mail system, there have been no adverse incidents affecting a Postal Service employee or the public. All etiologic agents are packaged and labeled according to federal requirements. Even so, ASCP selects only etiologic agents for which treatment is available.

The Postal Service should review mechanisms which would increase safety in the Postal system while maintaining its present important function of transporting medical specimen for purposes of diagnosis and consultation.

Instead of imposing an action as harsh as a ban, the ASCP believes that the Postal Service's efforts could better be directed toward enforcement of existing packaging requirements. The greater use of penalties for packaging violations would be a low cost enforcement mechanism.

While the present regulatory mechanisms have thus proven to be effective in ensuring safety for Postal Service employees and the general public, the ASCP recognizes that all regulations need to be reviewed for their efficacy from time to time. The Society would therefore support and assist in any efforts that might be undertaken for such a review and if needed, to update the current safety regulations. Additionally, as an educational organization, the Society is willing to provide its technical expertise to provide better instructive material to those who must comply with these requirements.

It is important to note that the knowledgeable professionals who regularly use the postal system to transport etiologic agents are not the cause of concern. These individuals can be counted on to follow the various packaging requirements. Enforcement of appropriate packaging requirements needs to be directed toward those individuals who, by virtue of not regularly using the mail for this purpose, may not be giving adequate consideration to the public health dangers of an improperly packaged shipment. Financial penalties would serve as an effective deterrent to violations.

The Society would be remiss if it did not caution that enforcement of the Postal Service's proposed ban would be very difficult. The Society suspects that undetected violations would increase dramatically, and would therefore present a much greater risk to Postal Service employees than the current rules which have served to protect these individuals for so many years.

> While the Postal Service should have the major responsibility to ensure that its customers are abiding by the rules, other Federal agencies as well as the private sector should be consulted.

The private sector can do a great deal to instill a sense of responsibility on the part of the medical community to ensure that packages are properly shipped according to federal regulations. As stated previously, the ASCP would be willing to provide technical assistance in this area. Other medical groups should be equally capable of assisting in this effort.

Several Federal Departments--e.g., the Departments of Transportation, Defense, and Health and Human Services--have a vested interest in ensuring that packages are properly shipped and have enacted regulations to achieve this goal. The Society recommends that the various affected agencies work together to arrive at a uniform policy for the necessary shipment of etiologic agents. Such activities would be far more productive and effective than unilateral action by the Postal Service to enforce a ban for which there is no support by public health agencies and the medical community.

The American Society of Clinical Pathologists submits this information in appreciation of the Subcommittee's interest in ensuring safety in the Postal Service system. It is the Society's opinion that safety concerns are managed by the current approach to packaging requirements. The Society is prepared to work with the Subcommittee and the Postal Service toward the ultimate goal of safety and quality health care.

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The ASCP is a nonprofit medical specialty society organized for educational and scientific purposes. Its membership numbers over 45,000 board-certified pathologists, other physicians, clinical scientists and certified technologists and technicians. These professionals recognize the Society as the principal source of continuing education in pathology and laboratory medicine as well as the leading organization for the certification of laboratory personnel. ASCP's certifying board registers over 140,000 certified laboratory professionals annually.

Mr. McCLOSKEY. Thank you, Dr. Rock.
Dr. Daggett, please.

STATEMENT OF PIERRE-MARC DAGGETT, CHAIRMAN, COMMITTEE ON CULTURE COLLECTIONS, AMERICAN SOCIETY FOR MICROBIOLOGY

Mr. DAGGETT. I am Doctor Pierre-Marc Daggett, chairman of the Committee on Culture Collections of the Public and Scientific Affairs Board of the American Society for Microbiology. On behalf of its 34,000 members, I am speaking today in opposition to the proposed postal ban which would impact thousands of scientific, medical, and industrial organizations.

In view of the testimony that has already been given here today, I am going to summarize our written testimony.

Mr. McCLOSKEY. We will accept your written testimony for the record, Doctor, and please summarize. Thank you.

Mr. DAGGETT. Thank you, Mr. Chairman.

ASM has actively supported and strongly and firmly believes that etiologic agents and other biological materials should be properly packaged and shipped, whether it be through carrier transport or through the Postal Service system, and it also believes that it is not unwarranted to periodically review whether the current safe and cost-effective system remains a cost-effective and safe system.

However, in view of the fact that there are no known cases in which properly packaged materials resulted in infections of handlers in the transport industry, and in view of the fact that there are no documented cases of increased problems in damaged packages, it is of only one possible conclusion, that the proposed ban is unwarranted and drastic at this time.

It should be noted that "etiologic agents" encompasses a very broad category of organisms, cells, and viruses. By definition, "etiologic agent" is any organism which may be potentially infectious to humans or, for that matter, other animals, but we are discussing humans here today. However, not all of them cause communicable diseases, and the risk for others is extremely small outside of special conditions. These special conditions which are required for infection are not usually encountered during the course of transport of cultures under properly packaged conditions.

In August of this year, after the proposed ban by the Postal Service, the ASM organized a meeting here in Washington, D.C., of a spectrum of representatives from organizations that represent individuals who would be concerned by this action as well as inviting outside observers from Federal Governmental agencies. In the course of that day-long meeting, we arrived at four recommendations which, as has already been noted, were passed along to the Postal Service. These four recommendations consisted of the following:

One, that the Department of Transportation and the Public Health Service, through the Centers for Disease Control, join the Postal Service in forming an interagency group to address a review of the current regulations, since all three agencies are currently involved in reviewing regulations and, furthermore, that this review process involve nongovernmental agencies to provide their exper-

tise and commentary on any proposed regulation; secondly, that there is a need for better defined terms and regulations—some of the terms, as has already been noted, are ambiguous, unclear, and do not clearly define levels of risk and levels of packaging that are required—three, that there be an education program for shippers, handlers, and receivers, involving again agencies of the Government and nongovernmental organizations; and, finally, the fourth recommendation was that penalties for violating current regulations be widely advertised, known, and that the violators be prosecuted.

I would like to thank you, Mr. Chairman, on behalf of ASM for this opportunity to comment, and, again, we would be willing to answer your questions.

[The statement of Mr. Daggett follows:]

STATEMENT

OF THE

AMERICAN SOCIETY FOR MICROBIOLOGY

TESTIMONY

of the

American Society for Microbiology

presented by

Pierre-Marc Daggett, Ph.D., Chairman
of the Committee on Culture Collections of
the Public and Scientific Affairs Board of the
American Society for Microbiology
before the

House Subcommittee on Postal Personnel and Modernization

of the

House Committee on Post Office and Civil Service

Hearing on

"Transportation of biological toxins and
etiologic agents through the mail"

October 5, 1988

90-365 284

AMERICAN SOCIETY FOR MICROBIOLOGY • 1913 I Street, N.W. • Washington, D.C. 20006 • 202/833-9680

Mr. Chairman and Members of the Subcommittee:

My name is Pierre-Marc Daggett and I am Chairman of the Committee on Culture Collections of the Public and Scientific Affairs Board (PSAB) of the American Society for Microbiology (ASM). The ASM is the largest single biological life science organization in the world with an active membership of over 34,000. Members of the ASM contribute to research and applied areas of infectious diseases, clinical microbiology, food technology, and biotechnology, as well as, molecular biology, host-parasite interactions and tissue culture. On behalf of the ASM, I thank you for inviting the Society to present its views at this hearing to continue the examination of transporting etiologic agents through the mail.

The ASM shares the viewpoint that etiologic agents must be properly and safely shipped. As recently as the May 1988 issue of ASM News, a monthly society publication, safe and proper procedures for the shipment of biological materials were reviewed (copy appended). Previously, at the 1986 ASM annual meeting, which was attended by over 15,000 scientists, the program included a round table on shipping and packaging of biologic materials. There have been other efforts to educate and encourage the ASM membership to employ proper and safe packaging practices. These efforts, which preceded the June 24, 1988 Federal Register notice by the US Postal Service of its intent to ban shipment of etiologic agents through the US mails, were intended to maintain an awareness among the ASM membership and to

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support a system of distribution of cultures, including etiologic agents, which has been both effective and, more importantly, safe.

It should be noted that etiologic agents encompass a broad category of organisms, cells and viruses which pose differing levels of risk. All etiologic agents by definition are potentially infectious to humans; however, not all cause communicable disease and the risk for others is extremely small outside of special conditions. Special conditions required for infection, not usually encountered during transport of cultures, include such factors, as dosage, aerosolization, stage of development, and in some cases transmission by a vector, e.g. mosquito or other biting insect. It must be emphasized that among the organisms considered to be etiologic agents are species which are part of the normal human flora or environment.

The biology of organisms which are etiologic agents and viruses was considered by the Centers for Disease Control (CDC) of the Public Health Service (PHS) in developing a classification system currently used which includes appropriate packaging requirements to eliminate or minimize risk in transport of these agents. The US Postal Service's proposed rule ignores the value of carefully considered distinctions recognized as reliable by experts within the field. The proposed regulation by the US Postal Service may have been an overreaction to an undocumented, yet apparently perceived, problem with current regulations and practices.

3.

Any change in or additional laws/regulations on the shipment of biological cultures and materials will have an impact of importance upon thousands of academic, medical, governmental, corporate and scientific organizations. The changes could result in major costs and thus have a significant economic impact.

Some areas which should be considered when assessing any proposed changes in current laws/regulations are highlighted by specific examples which follow:

The transport of both diagnostic specimens and cultures are vital to the national health. Although the proposed regulatory change by the US Postal Service, for example, indicates that there would be exemption for diagnostic specimens from clinical laboratories from the ban of shipment through the US mails, it is unclear whether a culture prepared as a part of diagnostic procedure would or would not be permitted. In fact, some states require that clinical laboratories send cultures of all microorganisms of public health significance to their state laboratory for further testing. Thus, for example, would a throat culture, which would be required in some cases by law to be sent to a state laboratory for identification, actually be permitted to be mailed?

Furthermore, many clinical laboratories are required by law to be tested for proficiency by successfully identifying coded samples of known cultures, including etiologic agents, received from an outside testing organization. At present, regulations established as a result of the Clinical Laboratory Improvement

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Act of 1967 require proficiency testing of all microbiology services. Any change could result in increased costs for these important programs.

Another aspect of the national health care system which would be impacted is the pharmaceutical industry. The pharmaceutical industry needs to both ship and receive etiologic agents. Pharmaceutical companies require strains which have developed resistance to antibiotics in addition to strains which have been discovered to be agents of disease.

It should be noted that guidelines for recombinant organisms require that all recombinant organisms be identified and shipped as an etiologic agent. In fact, most of the recombinant organisms in use today, which are the basis of the modern biotechnology, are not infectious agents. Changes in regulations could not only result in increased costs for both applied and research aspects of biotechnology, but might also retard developments in this rapidly developing area of applied science.

To restrict the transport of cultures and biological material to private carriers would currently result in cost increases of at least 10 to 15 times the cost of transport through the US mails. Where this increased cost would have to be absorbed in research or medical diagnostic services is not known although it will likely be by users of services. The implementation of the proposed regulation by the US Postal Service may result in carriers other than the US Postal Service not accepting etiologic agents and/or substantial increases

the cost over present rates for transport by alternative carriers.

These increase costs and difficulties may result in unmarked and perhaps even improperly packaged shipments through the US mail. Thus, if the proposed ban is instituted it could result in less safety in shipment of etiologic agents than is experienced under the current regulations.

The American Society for Microbiology considers the proposed ban by the Postal Service on the shipping of etiological agents through the mail an action of unwarranted concern, particularly since to date there has not been a single documented infection resulting from the proper practice of mailing such specimens. It is further recognized by ASM and other organizations that the US Postal Service, through providing the mechanisms for the shipment of etiologic agents and diagnostic specimens, has significantly contributed to the public health and well-being of the nation.

Clearly, continuation of this function by the US Postal Service is essential to the national health and economy. The most efficacious method of shipment of the agents is by proper packaging and shipping through the US mail as delineated by current regulations (42CFR Part 72) as promulgated by the Public Health Service [Centers for Disease Control].

It is in the best interest of all, shippers, handlers, and recipients, that the shipment of such material continue to be both safe and cost-effective. The current consensus standards which incorporate the above cited regulations were developed by

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the National Committee for Clinical Laboratory Standards (NCCLS) (HS-A2, "Procedure for the Domestic Handling and Transport of diagnostic Specimens and Etiologic Agents-2nd Edition"). This standard was published by NCCLS in January, 1985, and was adopted as an American National Standard by the American National Standards Institution in July, 1985.

The use of current packaging and labeling procedures and standards has proven to be safe and cost-effective. We nonetheless strongly support the need for periodic reassessment of the effectiveness of established procedures, which should be done with careful consideration of the entire body of experience and information developed over previous years.

Along with twelve other organizations, the ASM has submitted the following recommendations to the US Postal Service:

1. That since the PHS (CDC) and the Department of Transportation (DOT), both involved with various aspects of regulation in the shipment of etiologic agents and diagnostic specimens, are considering revisions to current regulations, it is recommended that the US Postal Service participate with the PHS (CDC) and DOT in forming a federal interagency committee to review the appropriateness of current regulations for packaging and shipping etiologic agents and diagnostic specimens so that guidelines/regulations may be established. It is also recommended that this committee seek the participation of nongovernmental

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organizations to assist in providing expertise and comment prior to the publication of proposed regulations. It is further encouraged that the interagency committee remain in existence to periodically review regulations, thus ensuring safe and cost effective transport of etiologic agents and diagnostic specimens.

2. That there be initiated a review of definitions describing etiologic agents and diagnostic specimens to identify more precisely potential risk(s) and define packaging requirements. Current terms and definitions have caused some confusion. It is unclear, for example, what should be considered a diagnostic specimen, and in turn, when that specimen should be labeled an etiologic agent. The term etiologic agent is broad and does not segregate hosts and levels of potential risk. More appropriate terms and accurate definitions should greatly improve the current system.

3. That there be established an education and training program for shippers, handlers, and recipients of etiologic agents and diagnostic specimens that emphasizes compliance with regulations, proper packaging and shipping. The program should involve governmental and nongovernmental organizations in order to educate the broadest possible range of individuals. The College of American Pathologists, the NCCLS, the

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American Society of Clinical Pathologists, and the Association of State and Territorial Public Health Laboratory Directors are important organizations that should be called on to assist in the development of such a program.

4. That there be enforcement with penalties for those who violate regulations on the shipping and packaging of etiologic agents and diagnostic specimens. Penalty actions must be made widely known. Procedures for prosecution of violators should be clearly established by the proposed Federal Interagency Committee. These procedures should be made known not only to postal employees but also to all those who ship agents and specimens through the mail.

Independently, ASM has also recommended that etiologic agents currently requiring a Public Health Service permit for transport be sent by registered mail. Shipment by registered mail involves minimal increases in cost while providing a means of tracking each shipment from the shipper to the recipient. In addition, out of our concern for the safe and effective transport of etiologic agents, we offer our resources and the expertise of our membership to further assist in the improvement of methods for shipment of etiologic agents.

It is important that there not be overreaction to any perceived problems with the current regulations governing the transport of etiologic agents. Current regulations for the

shipping of etiologic agents and diagnostic specimens through the US mail, have been successful and safe when properly followed. The recommendations cited here which we have made, along with others in some cases, can lead to an even better, safer system of cost-effective transport of cultures and biological materials, without overreacting to any perceived, albeit undocumented, problems with current standards and practices. Thank you for the opportunity to comment and I would be pleased to answer any questions.

Mr. McCLOSKEY. Thank you, Dr. Daggett, for an excellent statement, and I appreciate you gentlemen being here. It is obvious from your participation and interest and from your comments that you are already plugged into the CDC-Postal Service discussions. I would assume we could continue to rely on your expertise into the next year. That is the case, of course.

Mr. DAGGETT. That is correct.

Mr. McCLOSKEY. It is a little bit amazing to me, considering how routinely these substances have been shipped through the mails for years, that Mr. Miss, the postal worker at the Frederick facility who had a package sample burst in his hand, in effect, was the Paul Revere in the system to start generating the clarion call for increased safety enforcement and follow-up. Do you gentlemen at all share my amazement, or have your professional associations ever suggested to the Postal Service that at this point a year ago we should have been beyond Mr. Miss' ad hoc follow-up program of going out and buying the bucket, and the gloves, and the Clorox? I mean where have we been for all these years? I am not trying to blame or damn anybody, but isn't this somewhat amazing?

Dr. GAVAN. Well, it would seem to me that it would be somewhat amazing. I can only speak from our own experience both at the Cleveland Clinic Foundation as well as my association with the College of American Pathologists' proficiency testing program that knowledge of damaged packages has probably averaged over the last 10 or more years significantly less than 1 package per year, reports of such damage. So I would believe that to be the case.

Also, in our own reference laboratory—as Dr. Rock has indicated, our laboratory also serves as a reference laboratory—the frequency of improperly packaged and damaged specimens is virtually negligible. We do supply the materials to our clients.

Mr. McCLOSKEY. Have any of your organizations ever communicated with the Postal Service in previous years as far as providing an educational program? These accidents are rare, but there are still obvious statistical possibilities. I do think there are problems with packages more than once a year. We have heard 15, we have heard 30, we have heard various estimates, but particularly where we have concentrations of these biological specimens in certain post offices is where it will be statistically minimal.

Dr. GAVAN. Yes, Mr. Chairman, the College has offered its assistance in the past. We have also conducted actual training, not so much in the Post Office but in airline handling facilities. I believe in the Los Angeles area the College did conduct an educational program for the employees of that facility who handled a large number of samples for the College's proficiency testing program. Most of the samples at that time, and currently that contained etiologic agents came from the Los Angeles area, so therefore most of them were shipped out of the LAX airport, and that program was conducted, and, to my knowledge, it was a successful program.

Mr. McCLOSKEY. The Postal Service is working on this, and we all have to improve. But, obviously, whether it is your suggestions or anyone else's, somehow it just generally wasn't undertaken previously.

Mr. DAGGETT. Mr. Chairman, I think there is one thing that you have to bear in mind. Our organizations are not responsible for the

Postal Service. If there is a failure within the Postal Service system, then that is something that the Postal Service needs to address.

Mr. McCLOSKEY. I didn't say you were.

Mr. DAGGETT. But you are suggesting that, you know, it seems to be our job to go and monitor the Postal Service. One of the things we do as societies is that we periodically and actively review these procedures, and promote their use, and make sure that our membership are aware that these regulations exist; it is in everyone's interest to follow and to use them; and that certainly has been done by all the organizations that are involved in testifying here in this panel.

In terms of Paul Revere in the night kind of thing, it is like the kind of thing as though there is, you know, "The British are coming," and it is our job to say, "The British are coming." One is, we are not aware of a major problem in terms of damaged packages to begin with. Secondly, there is a difference between a package being damaged and the contents of that package being released. The third thing is that our role has been a role in terms of advocating the kind of information that should be forwarded to our memberships so that they are aware that they are in compliance with those regulations.

Mr. McCLOSKEY. I think I have a legitimate right to ask what your communications were with the Postal Service previously. It is not impugning or pejorative in any way. I think maybe you misunderstood the emphasis of my question, Doctor.

Mr. DAGGETT. Thank you. I must have misunderstood.

Mr. McCLOSKEY. Dr. Rock, you mentioned that there could be or there possibly is a problem in the cases of individuals not complying with regs, people not professionally trained and disciplined in the field. Could you elaborate on that a little bit and as to how that occurs?

Dr. ROCK. Surely, Mr. Chairman, I would be very happy to do that. I am speaking here from my experience as a laboratory director directing services for both hospitalized patients, and out-patients as well as specimens that come in through the mails or through private carriers.

Amongst the employees whom I am responsible for both in a supervisory and, I think, a moral sense, there are about three dozen who are very much in the position of the postal workers. They are the people who work with shipments coming in from the mails or from the various courier services, and I am very concerned. We have developed over the past five or six years some fairly straightforward procedures on what to do if a specimen leaks.

In general, I think the problems that we have encountered don't come from what I would call professional shippers. They don't come from the other laboratories, the large clinics, people who know what they are doing. The problems come from individual physicians' offices, and these are primarily diagnostic specimens. They are not shipping, you know, category 4 biological agents.

I think that the education problem for a great many health care workers is significant, one that I think all the professional societies who have testified here share part of the responsibility in helping to do. All physicians, to some extent, either in groups or individual-

ly, will ship specimens somehow to a laboratory for diagnostic services, whether it is to a State health laboratory for some communicable disease, or to my lab or Dr. Gavan's lab for regular diagnostic studies.

I have to say in the last few years the attention of the laboratory community has certainly been more heavily directed than previously on the issues of bio hazards and how to safely handle specimens. So that is one reason, I think, that so many of us responded to not only the proposed regulations but also are willing to help as much as we can with the educational aspects.

Mr. McCLOSKEY. Am I free to imply from your statement that the individuals, who are not consistently trained as far as the packaging and so forth, are more likely to be in individual physicians' offices?

Dr. ROCK. From my personal experience, that is correct, sir.

Mr. McCLOSKEY. I see. That is a suggestion for work and education in the medical community generally, getting the help of the AMA and so forth.

Dr. ROCK. That is correct.

Mr. McCLOSKEY. Dr. Gavan, you mentioned that it may be advisable to treat extremely virulent agents, particularly those for which there is no readily available cure, as a separate category from other etiologic agents. What are the implications for this as far as transmission of the HIV virus and so forth? What are we going to be ultimately deciding there?

Dr. GAVAN. As you know, the Centers for Disease Control has recommended certain precautions that laboratory workers should utilize. These precautions, of course, are for people who are actually handling samples. Basically, those precautions are one of containment. The regulations that we currently have and any improvement on those regulations, I feel, would provide for the adequate containment of the HIV virus as well as any other such agents.

I think my emphasis in my statement was really directed towards those agents that had been discussed earlier in the discussion today—that is, those which might be utilized in biological warfare areas, and those are the specific areas that I was referring to in that statement.

Mr. McCLOSKEY. Okay. In that regard, I have a follow-up question. Could I rely on your professional advice or expertise, as far as specific discussions, on bio-hazardous materials in the DOD? Obviously, concerns for the national security, would be respected; but, quite frankly, as an individual, I am going to need some help there.

Dr. GAVAN. I think that to the extent that I personally or the College of American Pathologists can provide information, given the appropriate access to information, we would be glad to give our opinion.

Mr. McCLOSKEY. I appreciate that very much.

Would anyone have any concluding remarks or suggestions, Dr. Daggett? Dr. Rock?

Mr. DAGGETT. I would like to point out that it was very gratifying to hear the comments from the Postal Service that it has been providing—I think it needs to be emphasized—it has been providing a very important service to the national well-being and health

and that they have certainly listened to the comments that occurred during the comment period, and I have listened very carefully to those. It is very encouraging to see that they are reacting to those comments along with the Public Health Service's Centers for Disease Control and would hope that that process continues into the future.

Mr. McCLOSKEY. I look forward to talking to you gentlemen hopefully early next year. I thank you very much and appreciate your being here. This hearing is adjourned.

[Whereupon, at 11:35 a.m., the subcommittee was adjourned.]

[The following statements were received for the record:]

STATEMENT OF PAUL J. SCHMIDT, PRESIDENT OF THE
AMERICAN ASSOCIATION OF BLOOD BANKS,
ON THE TRANSPORTATION OF TOXIC SUBSTANCES THROUGH THE MAIL,
BEFORE THE SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION,
COMMITTEE ON POST OFFICE AND CIVIL SERVICE,
U.S. HOUSE OF REPRESENTATIVES,
WEDNESDAY, OCTOBER 5, 1988

Chairman McCloskey and Members of the Subcommittee,

My name is Dr. Paul J. Schmidt. I am President of the American Association of Blood Banks. I am also President of the Southwest Florida Blood Bank, Inc., and a Professor of Pathology at the University of South Florida in Tampa, Florida. From 1954 to 1974, I held several positions at the National Institutes of Health, including Chief of the Blood Bank Department and Assistant Chief of the Clinical Pathology Department at the NIH Clinical Center.

On behalf of the American Association of Blood Banks (AABB), I am honored to submit this written testimony for inclusion in the record of the Subcommittee's hearings on the transportation of toxic substances through the U.S. Mail. The Association thanks the Chairman, Congressman McCloskey, and the Subcommittee for holding hearings on this important matter.

The American Association of Blood Banks (AABB) is a private, nonprofit, voluntary health organization. It is the professional medical society for those institutions and individuals engaged in blood banking and transfusion medicine in the United States. The AABB is the world's largest organization and the

only group in the U.S. devoted exclusively to these scientific disciplines.

AABB member facilities collect nearly half of the nation's blood supply and transfuse over 80 percent of all the blood collected in the United States. AABB members are located in all 50 states and over 40 foreign countries. Our more than 2,400 institutional members include community blood centers where blood and components are collected and prepared and hospital blood banks and transfusion services where patients are managed and components are transfused. AABB's individual membership approaches 8,000 and is multidisciplinary, including physicians, scientists, technologists, nurses, donor recruiters and administrative and management personnel. Our membership has a great breadth of expertise which varies from the scientific and clinical aspects of transfusion medicine to the many social and economic issues affecting blood banking.

Throughout its 41-year history, the American Association of Blood Banks has worked to maintain an adequate blood supply and make it as safe as possible for the American people. The AABB sets standards for and accredits blood banks and transfusion services. AABB's publication, Standards for Blood Banks and Transfusion Services, now in its 12th edition, is the nationally recognized standard utilized by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Department of Defense Military Blood Program as well as several

state licensing agencies. In addition, AABB's Technical Manual, first published in 1953 and currently in its 9th edition, is the primary resource text used worldwide for collecting, testing and transfusing blood. Further information describing the AABB and its programs is contained in the Fact Sheet attached to this statement.

The hearing today is a continuation of the Subcommittee's examination of the shipment of toxic substances through the U.S. postal system. At the first hearing on June 23, the Postal Service testified about the use of the mail for the transportation of extremely virulent agents. These agents, for which there is no readily available medical treatment or cure such as chemical or biological warfare materials, pose a serious hazard to postal employees.

On June 24, 1988, the United States Postal Service's proposed rule entitled, "Nonmailability of Etiologic Agents," which was published in the Federal Register. This proposed rule would prohibit the mailing of etiologic agents, or materials reasonably believed to contain etiologic agents, which are required to be labeled as an etiologic agent/biomedical material under Department of Transportation (DOT) and Department of Health and Human Services (HHS) rules.

The American Association of Blood Banks shares the concerns of the Subcommittee and the United States Postal Service regarding the transportation of toxic materials through the mail. As

a professional medical society, we are interested in practical and effective precautions that provide for the safe transportation of medical materials and supplies. As health care professionals, we are equally concerned about protecting our employees, postal workers and the public from potential hazards.

The AABB is concerned, however, with the serious effect this proposed regulation would have on existing health care practices. In conjunction with the College of American Pathologists (CAP), the AABB conducts a proficiency testing program for its member blood banks and transfusion services. These testing materials are labeled and packaged according to the appropriate federal regulations. The AABB and CAP mail the proficiency test serum in an inactive and noncontagious state. Most importantly, these materials have been safely transported by the U.S. Postal Service for many years, and there has never been one instance of illness or injury.

The Association agrees with the U.S. Postal Service that chemical and biological warfare materials should not be transported by mail. However, these materials should be treated separately from the routine shipment of medical etiologic agents which are properly packaged. As proposed, this regulation would affect the mailability of laboratory proficiency testing materials and those specimens shipped for diagnostic, consultation or testing purposes which do not pose a health threat when

properly labeled and packaged according to existing DOT and HHS regulations.

In addition to the unnecessary disruption of existing health care practices, this proposed regulation would undercut legislation already passed by the House and currently making its way through Congress.

On September 13, the House passed by voice vote and sent to the Senate H.R. 5150, the Clinical Laboratory Improvement Amendments of 1988. A similar measure, S. 2477, was ordered reported by the Senate Committee on Labor and Human Resources on August 10. Both bills require the Secretary of Health and Human Services to establish a national proficiency testing program for laboratories. This would include quarterly proficiency tests and national grading criteria, but it would allow the Secretary to recognize private proficiency testing programs. Without the U.S. Mail to send samples for required testing, increased costs could result in fewer qualified laboratories. This, in turn, could affect the availability of appropriate health care.

The AABB recommends that the Postal Service continue to permit the shipment of diagnostic specimens and proficiency testing materials in the U.S. Mail under the current strict DOT and HHS labeling and packaging regulations. Given the risk they present, chemical and biological warfare agents do not belong in the same category, and their transportation should be regulated separately.

The Association also supports programs to educate the health care community on appropriate packaging and shipping requirements. In addition, the AABB urges the expansion of educational programs for postal employees and the public on the low risk and proper handling of medical materials.

I thank the Subcommittee for the opportunity to comment on this subject and the U.S. Postal Service's proposed regulation. If there is any additional information the Subcommittee requires, the AABB stands ready to be of service.

SINCE 1925, AN INDEPENDENT, NON-PROFIT ORGANIZATION DEVOTED TO THE PRESERVATION AND DISTRIBUTION OF REFERENCE CULTURES

American
Type Culture
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TESTIMONY TO THE COMMITTEE ON POST OFFICE AND CIVIL SERVICE,
SUBCOMMITTEE ON POSTAL PERSONNEL AND MODERNIZATION

WEDNESDAY OCTOBER 5 1988

BY ROBERT E STEVENSON Ph.D.,DIRECTOR,
AMERICAN TYPE CULTURE COLLECTION, ROCKVILLE, MARYLAND.

Congressman McCloskey, members of the subcommittee, ladies and gentlemen.

The American Type Culture Collection appreciates the opportunity to participate in this hearing and respond to the invitation to make suggestions for the improvement in the shipment of etiologic agents.

The American Type Culture Collection wrote to the Post Office Department pursuant to the notice in the Federal Register of June 24, 1988 that in its opinion properly packaged and labeled shipments of etiologic agents posed no hazard and should not be prohibited. We have read of no documented instances of transmission of disease by a broken or compromised package and persist in our belief that observance of proper packaging and labeling by shippers is the best guarantee of safety.

We support the recommendations of the ad hoc committee convened by the American Society for Microbiology on August 15, 1988 and hope that a concertation of efforts by responsible officials from the Post Office, the Centers for Disease Control, U.S. Public Health Service, the Animal and Plant Health Inspection Service, U.S. Dept. of Agriculture, and the Department of Transportation would resolve the procedures likely to result in good compliance with existing federal regulations crafted to protect the public health and safety.

In our opinion, all packages containing etiologic agents or clinical specimens should be required to carry labels that they contain such material. This requirement should carry a provision that failure to comply is a misdemeanor punishable by a fine, imprisonment or both.

Further, shippers of infectious agents of CDC Class III agents or above must first secure a permit to ship or move such material in interstate channels. The packages containing such material would be labeled as above but would also bear the permit number of the shipper (or institution), a list of contents, and registered so that its movements could be traced. Failure to properly package could be punished by revocation of the permit and appropriate fines and/or waiting periods of permit suspension.

The Post Office would seem to be the most logical agency to implement such regulations and to enforce them, having taken due care to educating and assisting parties to learn and practice the proper procedures.

The medical and scientific communities have a great need for an efficient and safe means of exchange of biological materials and specimens that is reasonable in cost. They have relied upon the U.S. Mail for this and it would be a very severe setback to an important segment of our society to find these services unavailable or so costly that great increases in medical diagnosis fees are experienced and scarce research funds expended for unnecessary reasons.

Thank you for your attention and for your serious consideration of these issues.

R E Stevenson

IMPORTANT
INFECTIOUS SUBSTANCE
IMPORTANT
MUST BE OPENED
IN LABORATORY
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